



# Our position on The Nagoya Protocol and Access and Benefits Sharing of Genetic Resources

## What is the issue?

The Convention on Biological Diversity (CBD) is an environmental treaty adopted in 1992 that governs the conservation of biological diversity. Subsequent to the CBD, many countries 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 sustainable use of their genetic resources (GRs).

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 (eg financial value) arising from the use of GRs

The Nagoya Protocol is a legally binding treaty that creates obligations for countries that ratify it (Nagoya “Parties”). It provides the framework for implementing access and benefit sharing (ABS) – the third goal of the CBD. This requires members to take “appropriate, effective and proportionate” measures to ensure that GRs used for research and development (R&D) purposes within their jurisdiction have been accessed according to national laws.

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. Through the Nagoya Protocol, the international community has established a global framework regulating access to, and use of, GRs in R&D.

Stakeholders have recognised the potential for Nagoya-related laws and policies to have unintended consequences for public health, including potential delays in responses to seasonal and pandemic respiratory pathogens, and obstructing or delaying R&D into innovative medicines and vaccines. The Nagoya Protocol itself recognises the need for “due regard to cases of present or imminent emergencies that threaten or damage human, animal or plant health”<sup>i</sup>.

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

## What is GSK’s view?

- We recognise that protecting nature and preserving biodiversity is an important objective. From water to forests, our health is dependent on that of the ecosystems in which we exist. Putting health at the centre of action on climate and nature, we have set an ambitious goal to have a net positive impact on nature by 2030.<sup>ii</sup>
- Genetic resources (GRs) are an important tool in researching and developing new medicines and vaccines that make a difference to patients’ lives. As a healthcare company innovating to get ahead of disease, and taking bold steps to protect climate and nature, we are committed to using GRs in a responsible and appropriate way.
- The objectives of the CBD and the Nagoya Protocol can be mutually supportive of broader public health interests. We support the 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.

- GSK supports exclusions and exemptions for human pathogens in ABS-related national legislation and regulation. 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.
- 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. DSI should not be brought within the CBD or the Nagoya Protocol. GSK believes the use of data relating to a GR without physical access to the actual GR itself is a mechanism for reducing exploitation of GRs and should therefore be outside the scope of the CBD and Nagoya.

### **Background: CBD, Nagoya Protocol and public health**

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>iii</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>iv</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 DSI represents a crucial tool in scientific research. 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>v</sup> In response to concerns from some countries that use of DSI could undermine the benefit-sharing objective of the Nagoya Protocol, there are now calls for DSI to be brought within scope of the CBD and the Nagoya Protocol.

The use of GR data without physical access to the actual GR itself is outside the scope of the CBD and Nagoya. There is no evidence that the current system is undermining the benefit-sharing objective of Nagoya and no justified rationale for the need to include DSI. Moreover, incorporating DSI within Nagoya/CBD (moving beyond 'physical' genetic material) would have significant negative implications for public health and advancement of science including:

- dramatically restricting the data available in public databanks, as access to DSI would shift from an open, multilateral approach to a closed, bilateral one;
- introducing excessive obligations, which would deter potential users; and
- creating additional incentives to move R&D to non-Nagoya countries, benefitting non-Nagoya signatory countries and undermining the CBD's benefit sharing objective.

We instead support efforts at the national level to fully realise the current benefits of facilitating access to GRs through clearer national ABS policies.

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<sup>i</sup> [Text of the Nagoya Protocol \(cbd.int\)](https://www.cbd.int/nagoya/text/)

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

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

<sup>v</sup> *ibid*