

# GSK Public policy positions

## The Convention on Biological Diversity (CBD)

### The Issue

The CBD is an environmental treaty adopted in 1992 that governs the conservation of biological diversity and the sustainable use of genetic resources (GRs) over which states exercise sovereign rights. It has three main goals: (1) the conservation of biological diversity; (2) the sustainable use of its components; and (3) the fair and equitable sharing of the benefits arising from the use of GRs.

The Nagoya Protocol is a supplementary agreement to the CBD that entered into force on 12 October 2014. It is a legally binding treaty that creates obligations for countries that ratify it (Nagoya “Parties”). It provides the framework for the effective implementation of the third objective of the CBD, namely “*the fair and equitable sharing of benefits arising out of the utilization of genetic resources*”. Amongst other things, Nagoya requires members to take “*appropriate, effective and proportionate*” measures to ensure that GRs used within their jurisdiction for R&D have been accessed in accordance with provider country measures.

GRs are used in the research and development (R&D) of new medicines and vaccines. They are obtained from different sources and from different trade channels, and are used in different ways and at different stages of the R&D cycle. Through the CBD and Nagoya, the international community has established a global framework regulating access to, and use of, GRs in R&D. The framework allows Nagoya Parties to influence health related R&D on GRs, such as viruses and bacteria, including matters of urgent public health concern.

GSK supports the CBD’s access and benefit sharing objective; however, care needs to be taken to ensure the CBD and Nagoya are applied in a way that supports biomedical research and public health, not undermines them. This paper sets out our position on the CBD and related Nagoya Protocol, with a particular focus on issues relating to public health.

### GSK’s Position

- GSK supports the principles of access and benefit sharing (ABS) outlined in the CBD and the Nagoya Protocol. ABS and enforcement measures adopted by Nagoya Parties need to be appropriate, effective and proportionate in order to promote the fair and equitable sharing of benefits resulting from the use of GRs. These measures must also provide legal certainty to users, for example, by clearly defining what constitutes a ‘genetic resource’ and its ‘utilization’ in R&D.
- GSK supports the approach laid down in the CBD and Nagoya of leaving it to national governments to determine the conditions under which access to GRs should be given, and for the Parties concerned to mutually agree on the benefits to be shared. Given the CBD’s broad definition of GRs as “*any material of plant, animal, microbial or other origin containing functional units of heredity*” and the diversity of ways in which they - and materials which are in some way derived from them - are used in R&D, it is not possible to generalise as to the role that GRs play in biomedical research or to the value of any particular material to any particular project or product.
- Although GSK is not directly involved in bioprospecting programmes, when using GRs, we will seek to ensure any applicable ABS legislation or regulatory requirements of the provider countries of those GRs has been complied with.
- We support the exclusion of human GRs from the CBD’s scope and believe a similar exclusion should apply to GRs which are pathogenic to humans. In contrast to many other GRs, the CBD’s conservation and sustainable use objectives do not apply to GRs which cause disease and illness, as society is actively dedicated to their eradication.

- If pathogens which are harmful to humans are not excluded from the CBD or national laws, access to them must at a minimum be expeditious and avoid unreasonable and excessive obligations. Benefit sharing terms should facilitate and not hinder development of products for the prevention, treatment and cure of diseases. This is particularly true when the pathogens can be deadly.
- While we respect countries' rights to regulate access to seasonal flu strains, it is questionable whether development and subsequent production of GSK vaccines for seasonal flu fall within the CBD and Nagoya because both processes lack the key elements of novelty and innovation set out in those agreements.
- Digital Sequence Information (DSI) should not be brought within the CBD or Nagoya Protocol. The use of data relating to a GR without physical access to the actual GR itself is outside the scope of the CBD and Nagoya, while open access to DSI represents a crucial tool in scientific research

## Background

### Biomedical Research and Genetic Resources

A wide variety of biological materials is used in biomedical research. These range from human materials, including human pathogens, to animal and plant biological materials. They are obtained from various sources. Sometimes they will be indigenous and unique. More commonly, they will be cultivated or bred as staple commercial products and obtained through ordinary commercial channels. The various materials are used in very different ways and for very different purposes. For example:

- It is very rare for a biological material to be used in its natural form as an active component of a pharmaceutical. More usually, if biological materials are used at all, the active compounds in marketed products are extracted, purified and modified. The process of identifying an active compound in a natural product and developing it into a finished product is difficult, expensive, time-consuming and commercially risky.
- Biological materials are commonly used as tools in the research process. For example, CHO cells (derived from Chinese Hamster Ovaries), yeasts and other micro-organisms are used in screening assays.
- Biological materials are used in production processes. Some viruses used in vaccine production, for example, are grown in chicken eggs.
- Some research is based on publicly available information about a GR, although the resource itself is never used in the research. For example, GSK has been conducting research into a vaccine for malaria which will be piloting in some Africa countries during 2018. We obtained the genetic code of a malaria parasite from a US government authority which isolated the parasite from a US citizen in the late 1980s. He in turn had contracted the disease in one of several countries in Africa he had visited.

### Access to and Use of Genetic Resources

Article 15 of the CBD provides a framework for regulating access to, and fair benefit-sharing arising from, the use of GRs. Specifically, it recognises that:

- Authority to allow access to GRs lies with national governments and should be subject to national laws
- Access to GRs should be subject to the prior informed consent of the Contracting Party providing the resources (e.g., national government)
- National Governments may put in place mechanisms to ensure the fair and equitable sharing of the benefits arising from any R&D involving GRs
- Access and benefit-sharing should be on mutually agreed terms between the Contracting Party providing the GR and the proposed user. Contracting Parties should seek to facilitate access and not impose restrictions which run counter to CBD objectives

The Nagoya Protocol came into effect in October 2014. It arose from a 2004 mandate to a CBD Ad Hoc Open Ended-Working Group to “*elaborate and negotiate*” an international regime on access and benefit-sharing as envisaged under Article 15 of the CBD. It is a supplementary agreement to the CBD which seeks to clarify and harmonise ABS standards i.e. standards for ensuring Prior Informed Consent (PIC) for access to GRs and for agreeing any benefits to be shared arising from their use on Mutually Agreed Terms (MAT).

### Ensuring Compliance with ABS Agreements

Of note, Nagoya seeks to reinforce the CBD’s ABS obligations by introducing an obligation on countries in which GRs are used. Specifically, Parties to the Protocol are required to take “*appropriate, effective and proportionate*” measures to ensure that any GRs used in their jurisdiction that were accessed elsewhere were accessed in accordance with any local PIC and MAT provisions.

As with other elements of the Protocol, key to this provision’s success will be its interpretation and implementation. Enforcement by one Party of another Party’s unreasonable ABS legislation (including penalties) will undermine the spirit and intention of Article 15.

To implement the Nagoya Protocol, the European Commission adopted Regulation (EU) No. 511/2014 in April 2014. It entered into force in October 2014 and requires that those wishing to use GRs within the EU comply with onerous requirements relating to how those GRs were accessed.

### **The CBD, Nagoya Protocol and Public Health**

The objectives of the CBD and Nagoya Protocol can be mutually supportive of broader public health interests. However, because access to, and use of, GRs that can be vital to tackling disease can be prevented or controlled by ‘provider’ (and indeed ‘user’) countries, it is important that government legislation takes full account of public health interests. National laws must help facilitate, not obstruct, health innovation.

This was confirmed by a 2016 study by the WHO Secretariat which states:

*“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.”*

We agree and urge all countries to bear this in mind when drafting their own provider and user country laws. Unfortunately, the laws of several countries, including the EU, are likely to result in public health being impeded rather than promoted.

### Genetic Resources with Human Pathogenic Effect

The CBD defines biological resources to include “*genetic resources, organisms or parts thereof, .....with actual or potential use or value for humanity*”. It can be argued that viruses and bacteria which endanger human health have no inherent ‘*use or value for humanity*’. Nor, logically, do they appear to fall within the CBD’s objectives relating to ‘*conservation and sustainable use*’ of GRs. They should therefore be excluded from the scope of the CBD and Nagoya Protocol; and if this cannot be agreed, then access and use must be allowed on reasonable and expeditious terms.

### Seasonal Flu and the CBD

A well-established mechanism based on the WHO’s Global Influenza Surveillance and Response System (GISRS) exists for mitigating the public health threat posed by seasonal flu. Every year, the WHO decides which flu virus strains to recommend for northern and southern hemisphere flu vaccines. 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 required by the CBD and Nagoya Protocol.

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

Therefore, while we respect countries' rights to regulate access to seasonal flu strains, it is questionable whether development and subsequent production of the related vaccines fall within the CBD and Nagoya as they lack the key elements of novelty and innovation set out in those agreements. Furthermore, the timings involved in this process – from strain selection to vaccine manufacture - are extremely tight. Industry needs to be able to act quickly when the WHO decides on the composition of the seasonal virus. Any delay can significantly impact vaccine availability and national immunization programmes.

### Digital Sequencing Information

There is a well-established international framework for submitting Digital Sequence Information (DSI) and making it freely available on the internet to all. Open access to DSI represents a crucial tool in scientific research. However, in response to concerns from some developing countries that use of DSI could undermine the benefit-sharing objective of Nagoya, there are now calls for DSI to be brought within scope of the CBD and the Protocol.

The use of GR data without physical access to the actual GR itself is outside the scope of the CBD and Nagoya. Furthermore, there is no evidence that the current system is undermining the benefit-sharing objective of Nagoya and therefore no justified rationale for the need to include DSI. If there are shortcomings, it is largely due to the lack of provider country laws which facilitate access to GRs to in turn generate benefits. Once addressed, and clear and facilitative national ABS laws are put in place, concerns about the lack of benefit sharing related to GR access and use, should disappear.

Including DSI within Nagoya/CBD (moving beyond 'physical' genetic material) would have significant implications. It would either dramatically restrict the data available in public databanks, as access to DSI would shift from an open, multilateral approach to a closed, bilateral one, or else it would introduce excessive obligations which would deter potential users. It would also create additional incentives to move R&D to non-CBD countries, thereby simply serving to benefit non-CBD signatory countries and undermining the CBD's benefit sharing objective.

**March 2018**