

The Convention on Biological Diversity

The Issue

Biological materials, including genetic resources, are commonly used in the development 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 development cycle. This paper sets out GSK's position on the Convention on Biological Diversity (CBD), including our approach to the Access and Benefit-Sharing (ABS) provisions reflected in it and the Nagoya Protocol concluded in October 2010.

GSK's Public Position

- GSK supports the CBD's role in providing a framework for the conservation of biological diversity and the sustainable use of its components.
- We support the exclusion of human genetic resources from the CBD's scope and believe a similar exclusion should apply to pathogens which are harmful to humans. The CBD's conservation objective does not apply to them as society is actively dedicated to their eradication.
- GSK supports the CBD objective "*to provide fair and equitable sharing of the benefits arising from the use of genetic resources*". However, given the Convention's broad definition of "*genetic resources*" 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 research and development, it is not possible to generalise as to the role that genetic resources play in biomedical research or the value of any particular material to any particular project or product.
- GSK therefore supports the approach laid down in the CBD, the Bonn Guidelines and the Nagoya Protocol of leaving it to national governments to determine the conditions under which access to genetic resources should be given and for the parties concerned to mutually agree on the benefits to be shared.
- A careful balance needs to be struck when regulating access to genetic resources and the sharing of benefits arising from their use. The interests of all the various stakeholders must be taken into account. Go too far one way, and society risks inhibiting the search for medicines and vaccines to treat and cure diseases like HIV/AIDS, cancer, and malaria. Go too far the other, and the legitimate interests of countries and communities from where the genetic resources were sourced can be undermined.
- The best way of achieving the CBD's access and benefit-sharing objectives is for countries to introduce national laws governing access to their genetic resources and for mutually agreed contracts to define how any benefits arising from their use should be shared. This approach, which underpins the CBD, allows national Governments the flexibility to determine what best serves their national interests and allows users the ability to reach agreements which are appropriate to each particular case.

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GlaxoSmithKline's Position

- In this respect, GSK supports the Bonn Guidelines of 2002 which provide Governments with advice on how to set fair and practical conditions for access and benefit-sharing. We also support the *Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation* agreed in Nagoya in October 2010. The Protocol provides Governments with additional guidance on how to regulate access to genetic resources and to ensure the equitable sharing of benefits arising from their use.
- GSK is not directly involved in any bioprospecting programmes involving genetic resources. In the event that we do become involved, access to those resources will be obtained in accordance with local laws. If required by local laws, contracts will be negotiated with the appropriate party, at the time of acquisition, to ensure agreed benefits are provided. These benefits might amount to monetary payments and/or involve other types of benefits determined by mutual agreement on a case-by-case basis.
- Similarly, in the event that we collaborate with a third party that has collected natural products post-1993, GSK will take reasonable steps to ensure that both GSK and the 3rd party are entitled to use those products in the way contemplated by the collaboration.

BACKGROUND

1. 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, the active compounds in marketed products are extracted from biological materials, 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. Use of biological materials in this way, and bioprospecting to gather such materials, still occurs but is less common than it has been in the past.
- biological materials are also 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 information** about a genetic resource, although the resource itself is never used in the research. For example, GSK is currently conducting research into a vaccine for malaria. We obtained the genetic code of a malaria parasite from a US government authority which isolated the parasite from a US citizen. He in turn had contracted the disease in one of several countries in Africa he had visited.

2. The Convention on Biological Diversity

The CBD was initially signed by 150 Government leaders at the Earth Summit in Rio de Janeiro in 1992. Additional governments have subsequently signed up to it. The Convention 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 from the use of "genetic resources".

"Genetic resources" are defined in Article 2 of the CBD as "*genetic material of actual or potential value*". "*Genetic material*" is broadly defined as "*any material of plant, animal, microbial or other origin containing functional units of heredity*".

All UN discussions to date indicate that the Convention does not cover human genetic resources. GSK agrees with this view. We also feel strongly that there should be a similar exclusion for genetic resources which are harmful for humans. There is a societal interest in eradicating biological materials such as a virus, bacteria, prion or fungus that causes harm to its human host. This societal interest runs contrary to the CBD objective of conserving and ensuring the sustainable use of genetic resources. It therefore follows that these materials should fall outside of the various obligations set by the CBD, including its access and benefit sharing provisions.

Access to Genetic Resources

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

- Authority to allow access to genetic resources lies with national governments and should be subject to national laws
- Access to genetic resources should be subject to the prior informed consent of the Contracting Party providing the resources (eg, 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 genetic resources
- Access and benefit-sharing should be on mutually agreed terms
- Contracting Parties should seek to facilitate access and not impose restrictions which run counter to CBD objectives.

3. The Bonn Guidelines

Adopted unanimously by the signatories to the CBD in April 2002, the Bonn Guidelines on genetic resources (<http://www.biodiv.org/programmes/socio-eco/benefit/bonn.asp>) build on the principles captured in Article 15 of the Convention. They are voluntary and advise governments on how to set fair and practical conditions for users of genetic resources and associated traditional knowledge, along with advice on the roles and responsibilities of the various stakeholders. In return, the Guidelines stipulate that users of genetic resources should offer benefits such as profits, royalties, scientific collaboration, or training.

4. The Nagoya Protocol on Access and Benefit Sharing

Notwithstanding the role of the Bonn Guidelines in supporting Government ABS efforts, in February 2004 a CBD Ad Hoc Open Ended-Working Group was established to "*elaborate and negotiate*" an international regime on access and benefit-sharing. The negotiations concluded in October 2010 with agreement of the Nagoya Protocol on *Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation*.

The Protocol reaffirms the importance of legal certainty, clarity and transparency in systems regulating access to genetic resources and the fair and equitable sharing of benefits from their use. Importantly, it does not apply retroactively; it does not interfere with intellectual property systems and other regulatory mechanisms; and it affirms the key principle in the CBD that the terms associated with access and benefit sharing should be mutually agreed by the provider and user of the genetic resources.

GSK recognises that the Protocol is a product of compromise and that some provisions in the final text are unclear in scope. These provisions will require careful consideration, particularly as they are implemented into national law. If implemented appropriately, we believe the Protocol could establish a framework under which CBD Parties could introduce clear and transparent national laws on access and benefit-sharing.

5. Mutually Agreed Access and Benefit-Sharing Arrangements

Given the diversity of genetic resources and the way in which they are used in research and development, it is not possible to generalise as to the value of any particular material to any particular project or product.

For that reason, GSK supports the approach laid down in the CBD, the Bonn Guidelines and the Nagoya Protocol of leaving it to national governments to determine the conditions under which access to genetic resources should be given and for the parties concerned mutually to agree on the benefits to be shared. Agreements will cover such matters as the permitted use of the resources and the nature and timing of any benefits that are to be shared. This approach allows national Governments the flexibility to determine what rules will best serve their national interests and allows the stakeholders involved to reach agreement appropriate to each particular case.

Ensuring Compliance with ABS Agreements

To date, GSK has seen no evidence to suggest that an approach based on national laws and contracts would not meet the CBD objectives. That said, we recognise the concern expressed by some regarding the lack of a formal mechanism to ensure cross border compliance with national ABS laws. The Nagoya Protocol proposes a mechanism of mutual recognition of domestic legislation as a means of addressing this issue. Specifically, Parties to the Protocol are required to take “*appropriate, effective and proportionate*” measures to ensure that any genetic resources used in their jurisdiction have been accessed elsewhere in accordance with Prior Informed Consent (PIC) and that access and benefit sharing (ABS) has been on mutually agreed terms.

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

6. GSK Research Involving Natural Resource Materials

GSK's legacy companies were both involved in a number of collaborations around natural material collecting and screening. A number of these collaborations were established following the introduction of the CBD in 1992 and so involved ABS agreements. However, since the creation of GSK in 2000, techniques such as high-throughput screening of synthetic compounds are now generally considered more effective and efficient tools in GSK's drug discovery programmes. The majority of the ABS agreements struck before the creation of GSK have therefore lapsed.

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GlaxoSmithKline's Position

In the event that GSK becomes directly involved in any new bioprospecting programmes involving genetic resources, access to those resources will be obtained in accordance with local laws. If required by local laws, contracts will be negotiated with the appropriate party, at the time of acquisition, to ensure agreed benefits are provided. These benefits might amount to monetary payments and/or involve other types of benefits determined by mutual agreement on a case-by-case basis. In the event that GSK collaborates with a third party that has collected natural products post-1993, GSK will take reasonable steps to ensure that both GSK and the 3rd party are entitled to use those products in the way contemplated by the collaboration.

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