

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. More regulation of their collection and use is being considered at national and international levels.

As one of the world's leading pharmaceutical companies, GSK's position on the many issues linked with the use of genetic resources and associated traditional knowledge is increasingly of interest to the media, Governments and environmental NGOs. This paper sets out our position on the Convention on Biological Diversity (CBD) and our approach to the Access and Benefit-Sharing (ABS) provisions reflected in it.

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.
- GSK also supports the CBD objective "*to provide fair and equitable sharing of the benefits arising from the use of genetic resources*". However, given the diversity of biological materials and the many ways in which they are used in research and development, it is not possible to generalise as to the role they play in biomedical research or the fundamental value of any particular material to any particular project or product.
- A careful balance needs to be struck in seeking to define, implement and monitor appropriate 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 damaging 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.
- In GSK's opinion, 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 allows national Governments the flexibility to determine what guidelines will best serve their national interests and allows users the ability to reach agreements which are appropriate to each particular case.
- In this respect, GSK fully 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 believe that once countries have adopted local laws reflecting this advice, they will receive the protection and compensation envisaged under the CBD.

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GlaxoSmithKline's Position

- Notwithstanding GSK's support for national legislation and contracts based on the Bonn Guidelines, we recognise the CBD's mandate to "*elaborate and negotiate an international regime on access and benefit-sharing*". The resulting regime however, will need to be flexible enough to accommodate the diversity of genetic resources and the myriad ways in which they are used by different stakeholders and the value they add to the final product.
- GSK does not currently have any ABS agreements in place involving resources collected after 1993. 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.
- GSK does not accept the need to use patent law, in the form a disclosure requirement in patent applications, to help facilitate access and benefit-sharing. The legal and commercial uncertainties associated with a disclosure requirement would significantly reduce incentives to develop products which in any way involve "genetic resources". This could lead to a reduction in innovation (and the societal benefits that arise from it) as well as the benefits to be shared (ie. a key objective of the CBD)

BACKGROUND

1. Biomedical Research and Genetic Resources

A wide variety of biological materials is used in biomedical research. These range from human materials, through non-human materials found in humans (such as bacteria and viruses), through 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 then 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 products like aspirin and Taxol, are derivatives of biological materials, in other words, the materials were the "**starting point**" from which the final product was derived. This process of 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**. Gelatine, derived from cattle, is often used in capsules. Some viruses used in vaccine production are grown in chicken eggs.

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- 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, although it appears that some countries may now be questioning this. If this were to happen, it could have major implications for the pharmaceutical industry as all biomedical R&D involves human genetic resources at some point (ie. targets).

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.

Traditional Knowledge

The protection of Traditional Knowledge (TK) is not included as a formal CBD objective, nor is TK defined. Frequent reference, however, is made in the Convention to respecting, preserving and encouraging “customary use of biological resources in accordance with traditional cultural practices”.

The Bonn Guidelines (see *below*) – which provide guidance to governments on how to set up fair and practical ABS laws – subsequently developed the link between genetic resources and TK by confirming their scope as “*genetic resources and associated traditional knowledge*”. However, the Guidelines fall short of defining TK.

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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 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.

The Guidelines are voluntary and many countries have yet to adopt laws governing access to and use of their genetic resources. GSK believes that once countries have adopted such local laws, they will receive the protection and compensation envisaged under the CBD.

4. Access and Benefit-Sharing Agreements

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

For that reason, GSK supports the approach laid down in the CBD and in the Bonn Guidelines 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. In particular, we do not accept the need for the introduction of a disclosure requirement whereby patent applications would have to disclose the origin of genetic resources used in an invention, as a means for ensuring fair and equitable benefit-sharing. The patent system was designed to promote innovation and to provide economic development incentives. It was not designed to regulate behaviour. Furthermore, the difficulty of defining the precise scope of any disclosure obligation would create huge legal uncertainties for researchers and those who develop commercial products. These legal and commercial uncertainties would significantly reduce incentives to develop products which in any way involve "genetic resources". This would lead to a reduction in innovation (and the societal benefits that arise from it). It would also frustrate the Access and Benefit-sharing objectives of the CBD for if there is less research, then there will be fewer benefits to share.

GSK's more detailed position on this issue is outlined in a separate policy paper – "*Proposals for a Disclosure Requirement in Patent Applications*", October 2005.

5. CBD Discussions on an International ABS Regime

Notwithstanding GSK's support for national legislation and agreements as the basis for the ABS Agreements envisaged in the CBD and the Bonn Guidelines, we recognise the Conference of the Parties' mandate of February 2004 to the Ad Hoc Open Ended-Working Group on Access and Benefit-Sharing to "*elaborate and negotiate*" an international regime on access and benefit-sharing. The Group has been charged with considering both genetic resources and associated traditional knowledge. A deadline of 2010 has been set for agreeing a regime.

Scope & Nature of Possible International Regime (IR)

There is as yet no emerging consensus as to the nature (whether or not it should be binding,) scope or content of the regime. In devising any regime, GSK believes it should embrace the following fundamental principles:

- The IR should faithfully reflect, and should not go beyond, the CBD with respect to Access & Benefit-Sharing
- The IR should seek to implement the objectives and reinforce the framework of the CBD, not create new obligations or be inconsistent with the CBD.
- The IR should be prospective only and have no retroactive effect
- The IR should ensure legal certainty.

In addition, the Regime should reflect the following key elements:

- The IR should provide guidance as to how to achieve ABS objectives, not prescribe ABS rules
- The IR should apply only to genetic resources as defined in the CBD (unless otherwise limited), not a broader class of materials
- The IR should not extend to human genetic resources, and pathogens should be excluded
- The IR should not extend to derivatives

Negotiators should also take into account both the costs and benefits of the proposals to all stakeholders. Industry and others involved in research and development should be consulted as part of this process and GSK is ready to participate as appropriate. Without adequate consultation, there is a danger that the resulting regime will be inappropriate and unworkable, to the detriment of innovation in general and public health in particular.

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, while the few collaborations involving natural screening that GSK is currently involved in do not involve material collected post-1992.

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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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