Background

Biodiversity constitutes the totality and variety of life on earth and is the source of the natural raw materials and ecosystem services on which society and industry depends. Biodiverse materials, including genetic resources, are commonly used in the development of new medicines and vaccines. These materials may be obtained from sources ranging from cultivated commercially-produced stocks to indigenous, unique geographical locations. Genetic resources are used in pharmaceutical research and development, for example, to provide chemical hits/leads for progress towards new medicines and as the starting point for the creation of annual influenza vaccines targeted to the next predicted predominant influenza strain.

The Convention on Biological Diversity (CBD) is an international agreement which links traditional conservation efforts to the economic goal of sustainable use of biological resources. The treaty, initially signed by 150 Government leaders and brought into force in 1993, has three main goals:

- Conservation of biological diversity
- Sustainable use of its components
- Fair and equitable sharing of benefits arising from genetic resources

Genetic resources are defined in this context as “any material of plant, animal, microbial or other origin containing functional units of heredity, or actual or potential value”. According to the CBD, human genetic resources are excluded from in the definition of genetic resources.

The Nagoya Protocol (entered into force in October 2014) is an international agreement designed to implement the third objective of the CBD – “fair and equitable sharing of benefits arising from genetic resources”. The Nagoya Protocol was developed to create more predictable conditions for access to genetic resources, and helps ensure benefit-sharing when genetic resources leave the providing country – thereby creating incentives to conserve and sustainably use genetic resources.

To implement the Nagoya Protocol, the European Commission adopted Regulation (EU) No. 511/2014 in April 2014. This Regulation entered into force in October 2014 and requires that those wishing to access genetic resources demonstrate comprehensive due diligence.

The Commission has subsequently issued a draft Implementing Regulation laying down rules for the implementation of Regulation (EU) No.511/2014 as regards the register of collections, monitoring user compliance and best practices, which is currently subject to consultation.

AZ Group Global Public Policy Position Statement

AstraZeneca believes that a coordinated effort is required on the part of communities, governments and businesses to conserve global biodiversity. Unauthorised or unrestrained removal of natural resources can harm the ecology of the country concerned. While AstraZeneca supports the general principles set forth in both the CBD and the Nagoya Protocol, we are actively participating in discussions to clarify: the genetic resources in scope; the required due diligence obligations; and the impact of domestic access and benefit-sharing legislation and regulatory requirements recently issued by the EU.

As a corresponding member of the International Chamber of Commerce task force on the CBD, AstraZeneca contributed to discussions that support the development of international policy to ensure access to and equitable sharing of benefits from genetic resources.

When AstraZeneca becomes directly involved in bioprospecting programmes involving genetic resources, access will be obtained in accordance with local laws, where such laws exist, including obtaining prior consent and seeking to negotiate mutually agreed terms. We will use materials we obtained during bioprospecting in accordance with any mutually agreed conditions of use. Furthermore, in keeping with guidance from Regulation (EU) No. 511/2014, AstraZeneca will seek and keep related information and will make available the required diligence statements at the final stage of development of any product that emerges from the research.

In the majority of cases, AstraZeneca obtains genetic resources via a third party. When sourcing products within the scope of the Nagoya Protocol, AstraZeneca will take all reasonable steps to ensure that the third party who may supply us with materials has demonstrated appropriate diligence and has complied with all national access legislation governing the use of genetic materials.

Contd.
Development of AstraZeneca’s FluMist/Fluenz vaccine requires utilisation of wild type influenza strains provided by the World Health Organisation (WHO) obtained through the WHO global influenza surveillance network. As influenza strains are constantly changing, the virus strains included in seasonal influenza vaccines must be updated regularly to ensure that they match the circulating strains. AstraZeneca is working with international influenza vaccine associates to ensure that when manufacturers receive wild type strains from the WHO they are entitled to use them on terms consistent with the principles of the Nagoya Protocol.

**Links to Additional Resources**
- Convention on Biological Diversity
- Nagoya Protocol
- AstraZeneca Corporate Responsibility - Biodiversity
- Regulation (EU) No. 511/2014

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