

Nagoya Protocol: Access and Benefit Sharing

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 and unfairly disadvantage its inhabitants. AstraZeneca supports the general principles set forth in the Convention on Biological Diversity (CBD) and in particular its third objective: 'The fair and equitable sharing of the benefits arising out of the utilisation of genetic resources' in the context of the terms and conditions of the Nagoya Protocol. In this regard, we continue to actively participate in sector specific discussions to finalise definition of: the genetic resources in scope; the required due diligence obligations; and the impact of domestic access and benefit-sharing legislation and regulatory requirements issued by the EU. Previously, as an original corresponding member of the International Chamber of Commerce task force on the CBD, AstraZeneca contributed to discussions that supported the development of international policy to ensure access to and equitable sharing of benefits from genetic resources.

If 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 informed 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 due diligence statements at the final stage of development of any medicinal product that emerges from the research. In most cases, AstraZeneca obtains genetic resources via a third party. When sourcing items within the scope of the Nagoya Protocol, AstraZeneca will take all reasonable steps to ensure that the third party who may supply us with such items has demonstrated appropriate due diligence and has complied with all national access legislation governing their access and use. Bespoke AstraZeneca supporting tools and resources have been developed to assist with procurement decisions.

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 and Response System (GISRS). 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. This process requires approximately 6 months from WHO seasonal strain recommendation to vaccine delivery. Given this time constraint and potential limitations to fulfil legal obligations under the Nagoya Protocol, AstraZeneca continues to work with international influenza vaccine associates to ensure that when manufacturers receive wild type influenza strains from the WHO they are entitled to use them on terms consistent with, but not delayed by, the principles of the Nagoya Protocol. AstraZeneca also supports global stakeholders working to gain agreement that the WHO GISRS is exempt from the Nagoya Protocol as a specialised international access and benefit-sharing instrument under Article 4.4 of the Nagoya Protocol.

Links to Additional Resources

- [AstraZeneca Nagoya training video](#)
- [Convention on Biological Diversity Nagoya Protocol](#)
- [AstraZeneca Environmental Sustainability Regulation \(EU\) No. 511/2014](#)
- [ABS Clearing House](#)

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