

The Importance of Access and Benefit Sharing for the Life Science Industry

November 2022



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Introduction

The Nagoya Protocol provides a framework for the effective implementation of one of the three objectives of the Convention on Biological Diversity: the fair and equitable sharing of benefits arising from the utilisation of genetic resources.^{(a)(b)} It recognises that benefits derived by users of genetic resources should be shared with those who provide them, with the ultimate objective being the conservation and sustainable use of biological diversity.

Scope

Access and benefit sharing (ABS) regulations apply in many parts of the world when research and development (R&D) is conducted on genetic resources and / or associated traditional knowledge. A genetic resource is any material of plant, animal, microbial or other origin which contains functional units of heredity and is of actual or potential value. These regulations apply to both commercial and non-commercial activities spanning a variety of market sectors, including:

- Pharmaceutical
- Biotechnology
- Cosmetics
- Food and feed
- Research institutions



Obligations

User obligations under ABS regulations vary depending on the location where genetic resources and / or associated traditional knowledge are accessed and where they are utilised. In the EU and UK, compliance measures include the requirement to:^(c)

1. Exercise due diligence
2. Seek and keep the information relevant to ABS for 20 years after the end of the period of utilisation, and transfer this to subsequent users
3. Submit a due diligence declaration at the stage of research funding
4. Submit a due diligence declaration at the stage of final product development

Repercussions for Non-Compliance

Failure to comply with ABS obligations vary and will depend on the jurisdiction and type of non-compliance. Potential enforcement action may include:^(d)

- Advisory letters
- Compliance notices
- Stop notices
- Variable monetary penalties
- Enforcement undertakings

Note: (a) <https://www.cbd.int/>
(b) <https://www.cbd.int/abs/about/>
(c) <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32014R0511>
(d) <https://www.legislation.gov.uk/uksi/2015/821/contents/made>



Environmental, Social and Governance (ESG)

It is a legal requirement to comply with applicable ABS regulations. By adopting best practices to support ABS compliance, organisations can play an important role in promoting the conservation and sustainable use of global biodiversity. This approach can bolster overarching efforts as part of wider ESG considerations, including supporting the attainment of United Nations Sustainable Development Goals.^(e)

Case Study

ABS agreements between the community of Falealupo, Government of Samoa and foreign parties are considered as notable success stories. Agreements were signed for the purpose of R&D and bioprospecting linked to traditional knowledge from local healers and the local plant 'mamala' for HIV AIDS research.^(f) Benefits shared as a result of these ABS agreements have been used to support conservation of rainforests, as well as the construction and maintenance of local schools and healthcare clinics.

How We Can Help

The KPMG Life Science Regulatory Solutions team has expertise in supporting compliance with ABS regulations, and can provide advice in terms of understanding scope and how to fulfil required obligations. In addition, the team offer strategic regulatory advice to life science organisations throughout key product development stages, from early phase planning to launch and compliance for approved products across critical markets internationally.



- Note:
- (e) <https://absch.cbd.int/api/v2013/documents/22130401-0F0C-688C-1548-C6E4F1E53BE1/attachments/213523/Compendium%20-%20The%20contribution%20of%20ABS%20to%20the%20Sustainable%20Development%20Goals.pdf>
 - (f) <http://nbsapforum.net/knowledge-base/best-practice/samoa%E2%80%99s-access-and-benefit-sharing-success-story-local-communities>

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Document Classification: KPMG Public

CREATE: CRT144768A