Putting in practice the Nagoya Protocol: Issues and approaches for pharmaceutical companies in Germany

Workshop invitation

Since the adoption of the Nagoya Protocol on Access and Benefit Sharing (ABS), new rules for biodiversity-based innovation have been adopted in Germany and other countries around the world. These rules govern how companies acquire samples of plant, animal or other biological material or compounds, and may establish requirements for payments or projects based on resulting benefits.

But what do these rules mean for companies sourcing biological material for research and development for phytopharmaceuticals, active ingredients or biopharmaceuticals? How should concepts such as "utilization of genetic resources" be interpreted? What changes are required in research, development and supply chains? How does a company set up ABS systems? What are available tools? This workshop aims to support companies in navigating ABS rules and advancing procedures and practices for compliance with ABS in Germany and other countries.

Who should participate?

This workshop is tailored for companies producing, sourcing, developing or commercializing ingredients, products and services from biodiversity in the pharmaceutical sector – particularly staff members involved in research, product development, sustainability, regulatory compliance, supply chain management and supplier relation activities.

What can you expect from the workshop?

- Introduction to ABS concepts, principles and practical implications
- Interactive exchange on specific issues for the pharmaceutical sector
- Guidance on setting up procedures for due diligence on ABS
- Opportunity for questions and experience sharing

<u>Agenda</u>

10:00-10:20	Introductory session
10:20-11:00	The basics of ABS
11:00-12:30	Due diligence on ABS:
	 What are relevant rules in the European Union and Germany? Which are obligations for companies working with natural ingredients in pharmaceuticals? What type of issues and challenges commonly arise in this sector?
12:30-13:30	Lunch
13:30-15:00	Steps for due diligence on ABS:
	What are strategies and tools for developing due diligence systems?What lessons can be learnt from a practical case?
15:00-15:15	Coffee break
15:15-16:00	Closing: Challenges, opportunities and next steps

Survey for participants

With your registration for the workshop on the Nagoya Protocol on access and benefit sharing (ABS), please fill out the following survey. The information is collected to allow us to understand participants' level of awareness, expertise and experience on ABS. It is also an opportunity for participants to put forth specific questions or cases to be discussed.

Please note the information will be considered and communicated only in an aggregated manner, with no identification of any specific participant or company.

Thank you!

1.	Please fill out the following information on yourself and the company or association you are affiliated with:
	Name of participant:
	Position:
	Company or association:
2.	Which of the following activities are relevant to your company?
	Cultivating, collecting or sourcing biological material as raw material
	☐ Bioprospecting for new plants or other biological material with potential application in phytopharmaceuticals and drug development
	☐ Developing phytopharmaceutical ingredients and/or formulations
	☐ Characterization and/or synthetization of biological material in drug development process
	☐ Pre-clinical research on pharmaceutical products
	Developing or producing biopharmaceuticals
	☐ Other activities linked to biodiversity-based R&D, such as:
3.	Have you participated in training workshops on ABS before?
	☐ Yes ☐ No
4.	How would you rate your understanding of ABS rules and their practical implications?
	Select
5.	How often are you faced with ABS-related issues in your work?
	Select
6.	What kinds of ABS-related issues arise in your work?
	☐ Defining applicability of ABS requirements to access raw material or ingredient
	☐ Finding reliable and up-to-date information on ABS
	Responding to questions from suppliers or clients
	☐ Securing ABS-related permits and contracts directly in provider country
	☐ Ensuring suppliers have necessary ABS-related permits and contracts

	☐ Explaining ABS to other company staff
	☐ Integrating ABS into company policies or procedures
	Other ABS-related issues and questions, such as:
7.	How would you rate your company's understanding of how ABS rules apply to its activities?
	Select
8.	Which of the following measures related to ABS have already been taken by your company?
	☐ Policy on ABS
	☐ Due diligence procedures on ABS
	☐ Staff training on ABS
	☐ Supplier questionnaire on ABS
	Assessment of ingredients or projects on ABS
	☐ Access permits
	Other measures related to ABS, such as
9.	Please describe any challenges or opportunities related to ABS identified in the work of your company:
10.	the work of your company: Do you have any suggestions for issues that would be useful to discuss in the