

Creating enabling environments for successful partnerships in sourcing of genetic resources and product development

Reflection paper

to the Business Dialogue Meeting on Cooperative Business Conduct and Access and Benefit-sharing (ABS) in Africa, Copenhagen, 28 September 2010.

A. Background

“... the fair and equitable sharing of the benefits arising out of the utilization of genetic resources” is one of the three objectives of the Convention on Biological Diversity (CBD). Benefits include “appropriate access to genetic resources and ... appropriate transfer of relevant technologies” Article 1 of the CBD.

This objective was to satisfy both industrialised countries who wanted to obtain a global commitment to the conservation of biological diversity as well as access to these resources and developing countries who wanted benefit-sharing for the utilisation by other parties of their genetic resources. Genetic resources were then at the time of the final negotiations regarded as an upcoming resource for companies in key sectors such as medicine, healthcare and cosmetics, crop protection, crop development, and industrial enzymes. Developing countries further argued that traditional knowledge on “how to use genetic resources” should also only be applied commercially with the prior informed consent of the holders of such knowledge and with benefit-sharing.

The goal was to establish a just mechanism that both would allow for development and marketing of genetic resources and their biochemical derivatives profitably and that would provide an economic and social incentive for conservation and sustainable use of local biodiversity.

With its objective on ABS, the CBD was – and is – the most innovative and farsighted convention to conserve and sustainably use biodiversity at the time. The ABS framework however required elaboration in order to make it functioning. The for a long time and controversially negotiated **international ABS protocol** is to be concluded in October 2010 at the 10th Conference of the Parties to the CBD. With this ABS regime at the global level a normative and operational framework is expected to be established – with the obligation to the signatories to translate it in national legislations and regulations.

B. African Challenges

Currently, the potential of ABS to contribute to national and local economic development as well as poverty alleviation in especially Africa is not yet being realized.

Barriers:

1. The absence of effective **ABS policies and legislative frameworks** at the national level.

Legal certainty and basic infrastructure are both requirements for investment and valorisation of genetic / biochemical resources. Examples from Asia^{1,2} highlight that R&D by partners such as universities, private

¹ Novartis' successful natural products research is based on external partnerships with countries of high biological diversity. Collaborations are established in China and Thailand with the Biotec Research Center in Bangkok (isolation of microorganisms and pure natural products), the Shanghai Institute of Materia Medica (isolation of molecules from plants of China's traditional medicine) and Kunming Pharmaceuticals (production of Coartem/Riamet, an anti-malaria drug based on traditional Chinese

and public research institutions in provider countries are key for the successful valorisation of genetic and biological resources (GR/BR), especially in the (phyto-) pharmaceutical sector.

In this regard with inter alia the support of the *ABS Capacity Development Initiative* steps are being made in a number of African countries to set up national ABS rules and regulations, in order to provide the necessary legal certainty for both providers and users of genetic/biochemical resources.

2. Limited **research and development capacities** to identify and pre-process genetic and biochemical resources of (potential) commercial interest in the provider countries

While legal certainty is established step-by-step, efforts to build up basic research and development infrastructure are still missing to a large degree.

Firstly, there are a lot of potentially marketable genetic/biochemical resources for export but human capacity and technical infrastructure for sourcing, identification, product development and supporting the commercialisation and investment processes are lacking. Significant development impact cannot be achieved when all steps of the value chain are outside provider countries.

Research and Development (R&D) facilities laboratories – where they exist – are generally underequipped in terms of human resources (quality/quantity) and technical equipment. R&D laboratories established for the valorisation of genetic and biochemical resources, i.e. identifying active compounds for phytopharmaceutical or biotech applications, can also be used for initial quality assessment, control, monitoring and improvement in the biotrade sector (food, beverages and cosmetics) as technology modules are comparable. Therefore one investment in infrastructure and skill development could contribute to improve market access in two sectors, the commercial utilization of genetic resources and broader biotrade.

Secondly, Africa owns a lot of traditional knowledge (TK) on genetic and biological resources bearing a considerable potential for product development in the food, cosmetic and pharmaceutical industries. However, TK in Africa is – unlike for example in Asia – not systematically recorded and therefore constitutes a potential resource which cannot adequately be valorised for screening, R&D and product development.

R&D based in Africa and a sensible approach to the use of traditional knowledge would allow for more proactive market access, and an upper level value chain achieved in Africa.

3. Insufficient focus on and public investment in sustainable **commercialisation processes and business partnerships.**

There is to date no co-ordinated effort to combine genetic/biochemical resources, traditional knowledge, ongoing national and regional development programmes as well as scientific scientific and academic knowledge into commercial outcomes that lead to realizing the potential of genetic/biochemical resources into economic development.

medicine). Novartis supplies Coartem at cost to the WHO for use in developing countries. More than 215 Million treatments have been applied since 2001, over half a million lives saved <http://hugin.info/134323/R/1212233/251465.pdf>

² The Munich based Bicolll GmbH is partnering with the Shanghai Institut of Materia Medica. The joint research resulted in “a unique and highly biodiverse pool of endemic Asian plants. This resource is the key for Bicolll's highly successful natural product compound library BILOBAC N”. - <http://www.bicolll-group.com/index.php?page=2000>

C. A way forward: Broadening the scope of capacity development from improving political and legal framework conditions to developing R&D skills and commercialisation infrastructures

There seems to be significant interest from commercial and non commercial researchers, corporate business and business associations to cooperate with African partners with regard to the valorization of genetic and biochemical resources. Some initial activities of research cooperation, such as research to research (R2R) and business to business (B2B), are already established. Therefore, in selected cases R&D capacity development could build on existing cooperation, trust and market knowledge supporting the successful development and market introduction of new products. However side- and upscaling of these experiences remains a challenge for today and the future.

As compared to scattered national and mostly under equipped and understaffed laboratories the establishment and promotion of more comprehensive R&D (partner-) facilities at the regional level – with a view to developing into e.g. regional centres of excellence – may be a way to improve R&D quality at reduced costs and foster regional cooperation in the biotrade and ABS sector.

Key for the success of such regional R&D platforms will be firstly “harvest the low hanging fruits” instead of only “searching for the green gold”, i.e. the 20 year research project to develop a block buster drug with the high risk of failure. In many, surely not in all, cases focusing in the early R&D stage on improvements of readily marketable products could help to generate income and profit already in the second or third year which can be shared with the producers and be used to further improve their own R&D capacities.

Besides providing appropriate up to date technical laboratory infrastructure and equipment, the development of skilled human resources is key for a sustainable R&D set up. The necessary national/regional skill development, teaching and on-the-job training rely on R&D experts who are experienced: in (TK based) resource and lead identification, product development, marketing and placement. Hence in principle the often consecutive levels/steps of market accession for resource and product marketing require on the job capacity development, know-how and technology transfer:

- *Level 0 Identification of marketable resources and assessment of market potential*
- *Level 1 Quality control of marketed / marketable resources*
- *Level 2 Quality improvements (e.g. using different varieties of resources or refining the extracts)*
- *Level 3 Identification of active components for use as food additives, in phytopharmaceutical research or other applications.*

D. Aim of the Business Dialogue

This Business Dialogue aims to analyse and discuss barriers and potentials for promoting partnerships that foster R&D capacities and sustainable partnerships by identifying

- Legal, economic and R&D framework conditions in provider countries necessary for private sector engagement in genetic/biochemical resources in African countries.
- R&D particularities and possible co-operation approaches of different ABS “affected” sectors
- Existing technical and/or financial instruments available to support partnerships
- Needs for further developing or creating instruments to support such partnerships
- Possible contributions to international sustainable development by such partnerships