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FINAL REPORT

IMPLEMENTATION OF THE NAGOYA PROTOCOL ON ACCESS TO GENETIC RESOURCES AND BENEFIT SHARING – THIRD PHASE

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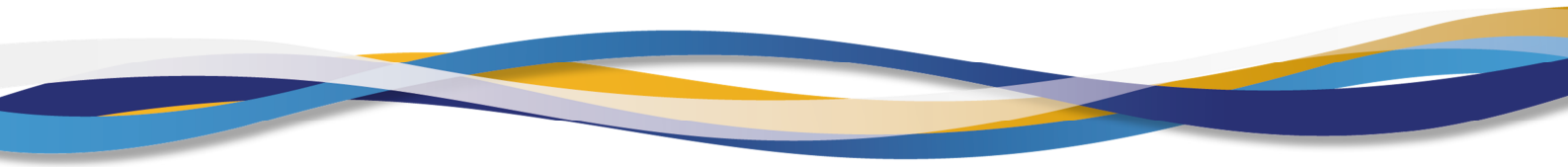

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TABLE OF CONTENT

EXECUTIVE SUMMARY 2

ACKNOWLEDGEMENTS & DISCLAIMER 4

1. APPLICABLE LEGAL FRAMEWORK 5

1.1. INTERNATIONAL ABS LEGAL FRAMEWORK 6
1.1.1 COMPLIANCE FRAMEWORK IN THE NAGOYA PROTOCOL 6
1.2 REGIONAL ABS LEGAL FRAMEWORK: EU ABS REGULATION 11
1.3 BRAZILIAN ABS LEGISLATION 13
1.3.1 DEFINITIONS 14
1.3.2 ACCESS PROCEDURES 15
1.3.3 BENEFIT-SHARING 16
1.3.4 COMPETENCES 17
1.3.5 CONCLUSIONS 17

2 CODES OF CONDUCT, GUIDELINES, BEST PRACTICES AND PRIVATE STANDARDS ON ABS 19

2.1 BASIC RESEARCH CODES OF CONDUCTS 22
2.1.1 INTRODUCTION TO EX SITU COLLECTIONS 22
2.1.2 NETWORKS OF COMPLIANCE 23
2.1.3 TRACKING AND MONITORING – DATA MANAGEMENT SYSTEM 25
2.1.4 TRAINING OF INTERNAL STAFF 29
2.1.5 SHARE OF SCIENTIFIC RESULTS AND DATA 29
2.2 INDUSTRY CODES OF CONDUCT, GUIDELINES AND BEST PRACTICES 30

3 THE PHARMACEUTICAL SECTOR IN BRAZIL 33

3.1 MARKET SIZE AND POTENTIAL MARKET 33
3.2 EXPORTS AND IMPORTS 34
3.3 RESEARCH AND INNOVATION 35
3.4 SOURCE OF RAW MATERIALS 36
3.5 PIPELINE COMPLEXITY 37
3.6 REGULATORY PROCESS 38

4 A SYSTEM FOR MONITORING AND TRACKING 40

4.1 EFFECTIVENESS OF A SYSTEM OF TRACKING AND MONITORING 41
4.2 THE MONITORING AND TRACKING SYSTEM 42
4.3.1 RAISING AWARENESS AND IMPROVING KNOWLEDGE OF THE SECTORS AND THEIR BEST PRACTICES 42
4.3.2 SCIENTIFICALLY BASED TRACKING: GLOBALLY UNIQUE IDENTIFIER 46
4.3.3 CONTRACTUAL TOOLS FOR MONITORING AND TRACKING 48
REPORTING DUTIES 50
THIRD PARTIES TRANSFER 52
MATERIAL TRANSFER AGREEMENT 54
CONCLUSIONS 58

BIBLIOGRAPHY 60

ARTICLES AND BOOK 60
REPORTS AND OFFICIAL DOCUMENTS 63

EXECUTIVE SUMMARY

The aim of this study is to provide an analysis of codes of conduct, best practice, and guidelines related to access and benefit sharing arising out of the utilization of genetic resources (GR); and, on the basis of applicable international and national law, to provide ideas for a system for tracking and monitoring genetic resources along the whole value chain – with specific focus on the continuity of information transfer throughout possible boundary crossings between basic research, applied research and product development. It will also look into the integration with the Access and Benefit-sharing (ABS) Clearing House (CH) set up in line with the provisions of the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of the Benefits arising from their Utilization to the Convention on Biological Diversity (Nagoya Protocol). For illustrative purposes and according to the Terms of Reference (ToR), the study will be grounded on the analysis of the Brazilian pharmaceutical sector and its value chain.

The first chapter aims at illustrating the applicable legal framework to the study, that is to say the international, regional and national access and benefit-sharing laws and regulations. This chapter will highlight the obligations that are already binding to genetic resources' provider and user states, and to users, in terms of monitoring and tracking. It will then introduce the Brazilian new draft ABS legislation that is now undergoing the legislative process before its probable adoption by the Brazilian Congress. With the new draft, the ABS legislation in Brazil will shift its governance model from an authorization model to a declaration one, with the exception of foreign actors not associated with any Brazilian entity, for which the authorization procedure is being kept in place.

The second chapter describes the main elements of existing codes of conduct, guidelines and best practices on ABS adopted from a wide array of actors, introducing in details the most relevant with regards to the pharmaceutical sector. The analysis tries to focus on the features that are more important from the point of view of tracking and monitoring the GR in the whole value chain. The chapter also stresses the importance of private standards as best practices that are implemented voluntarily by the sectors to comply with sustainability and ABS obligations.

The third chapter will briefly introduce the peculiarities of the Brazilian pharmaceutical sector: its market value, the complexity of its value chain, the structure of its research and development and the Brazilian regulatory process through which a company is authorized to sell a pharmaceutical product in the market.

Tracking and monitoring are significant components of the process of verifying whether or not genetic resources are being utilized in the form that was originally

agreed upon. Chapter four analyses this peculiar issue within the framework of the present study, and tries to propose concrete solutions and different options on how to better track the use of GR and monitor the compliance of their use with the Mutually Agreed Terms (MAT) negotiated with the provider country. The proposed monitoring and tracking system will not only consider the specificities of the illustrative Brazilian pharmaceutical value chain, but also be grounded on the obligations that are already in place at the international, regional and national level and build upon existing actors' practices analysed in the second chapter of this study.

The approach taken by the present study is that tracking is only one part of the broader framework that aims at ensuring ABS compliance, and it cannot work in isolation from the other features of the framework. This framework is made up of different tools that are fundamental for a tracking system to operate and therefore to ensure monitoring of GR use, including pre-requisite of awareness of stakeholders; contractual tools for monitoring and tracking; the use of a unique identifier; and institutional monitoring through the checkpoints up to the ABS Clearing House. The proposed monitoring and tracking system is focusing on two main features:

- The three interoperable and interconnected databases of the registry, and of the authorizations' and notifications' databases established by the draft ABS Brazilian legislation, that are to be linked with the MTAs signed by the users in cases of transfer of GR; the Clearing House databases and the Internationally Recognised Certificates of Compliance (IRCC); and the global unique identifier.

and

- The use of a scientifically based global unique identifier when possible, which documents regulating its use and with the actual scientific information related to the GR, when possible.

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1. APPLICABLE LEGAL FRAMEWORK

"Tracking (tracing) systems involve procedures that follow the international movements of genetic resources, from original provision all the way up to inclusion in a commercial product or other inventions, including those applying for patent protection". "Monitoring refers to a regular assessment of the functioning of the access and benefit-sharing system as a whole." (Eaton et al. 2007, p. 21).

For the purpose of the present study the international legal framework related to access and benefit-sharing (ABS), the national and regional relevant ABS legislations in place (the European Union and the Brazilian legal framework on ABS) have been looked at, as they are the applicable legal framework where the tracking and monitoring system for the flow of genetic resources needs to be rooted in. That is why this chapter will introduce only the main features related to tracking and monitoring of the Nagoya Protocol on Access and Benefit-sharing (NP); as well as of the Regulation of the European Parliament and of the Council on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union (EU ABS Regulation). It will then illustrate the features of the new draft ABS Brazilian legislation, which has not yet been adopted by the Congress.

This overview, necessary to identify the monitoring and tracking obligations that are already binding the different actors involved, is the starting point for the development of the proposed monitoring and tracking system (Chapter 4).

1.1. INTERNATIONAL ABS LEGAL FRAMEWORK

The Nagoya Protocol, adopted in 2010 and entered into force on October 12 2014, was negotiated under the auspices of the Convention on Biological Diversity, signed in May 1992. Having entered into force in December 1993, the Convention is the first international conservation agreement addressing biological diversity as a whole rather than through sectoral approaches focusing on specific species, ecosystems or sites. Its objectives are the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising from the utilization of genetic resources (CBD, Article 1). The Convention is a framework treaty setting down the basic principles Parties have to follow in providing for the conservation and sustainable use of biological diversity and in granting access to their genetic resources, leaving to each Party to implement those principles in its own territory and according to its own policies and legislations.

The Protocol is the instrument for implementation of the access and benefit-sharing provisions of the Convention on Biological Diversity (NP, Article 4.4), especially article 15 of the CBD on Access to Genetic Resources.

Article 15 of the CBD only covers genetic resources and does not apply to traditional knowledge. Indeed Article 8(j) of the CBD, the provision explicitly addressing traditional knowledge associated with genetic resources focuses on the preservation and maintenance of such knowledge. “However, Article 8(j) includes a reference to ABS, thus establishing a link to Article 15. This link provided a basis for the inclusion of traditional knowledge associated with genetic resources in the negotiations on the ABS regime, therefore in the Nagoya Protocol.” (Greiber et al., 2013, p. 109).

The Protocol strengthens the CBD obligation “to promote and encourage research which contributes to the conservation and sustainable use of biological diversity, particularly in developing countries (CBD, Article 12(b))” prescribing the adoption of “simplified measures on access for non-commercial research purposes, taking into account the need to address a change of intent for such research (Nagoya Protocol, Article 8(a))”.

1.1.1 COMPLIANCE FRAMEWORK IN THE NAGOYA PROTOCOL

Alis. The three pillars of ABS are access, benefit-sharing and compliance (Greiber et al., 2013). “On the one hand, users need clear, transparent, predictable, equitable, and efficient legal and administrative frameworks to secure legal clarity and certainty when accessing genetic resources and traditional knowledge associated with those resources. Without such legal certainty, researchers and industries will be less eager to invest in bioprospecting activities. This will lead to less access and as a consequence to less benefit-sharing in the end. Furthermore,

lack of legal clarity will make it difficult for users to fully comply with the providers' ABS requirements, leading to controversy and allegations of misappropriation or misuse. On the other hand, the main interest of providers lies in the fair and equitable sharing of the benefits arising from the utilization of their genetic resources and traditional knowledge associated with those resources. Providers therefore need effective measures to ensure that users in their jurisdiction do not misappropriate or misuse genetic resources and traditional knowledge associated with those resources. Thus, they aim for compliance with their domestic ABS regime in general and with the MAT for benefit-sharing in particular" (Greiber et al., 2013, p. 13-14). "When genetic resources/traditional knowledge associated with those resources are transferred from a provider to a user country, neither the provider nor the user State alone can take appropriate measures that ensure an efficient and effective ABS regime. While provider States have sovereign rights over their genetic resources, due to the territoriality principle they are hampered in monitoring and controlling the downstream process of utilization. It is generally not possible to enforce provider countries' ABS legislation in user countries. The enforcement of ABS agreements in user State courts is possible, but very costly. User States again can be obliged to monitor and control the utilization of genetic resources/traditional knowledge associated with those resources within their jurisdiction. However, tracing back to provider countries is a great technical and administrative challenge, leading to high transaction costs" (Greiber et al., 2013, p.13).

The Protocol's system of compliance "is based on a mixture of international and domestic measures, including: basic obligations on users to respect national access laws, supportive monitoring measures, including through designated 'checkpoints', the issuing of internationally recognized certificate of compliance as evidence of legal acquisition in provider countries, and the future establishment of an international mechanisms to address compliance of Parties with their Protocol obligations in a cooperative and non-adversarial manner" (Morgera et al., 2013, p.8).

Article 15.1 on genetic resources and 16.1 on associated traditional knowledge are innovative: they require that "Parties shall take appropriate, effective and proportionate measures to provide that genetic resources (art. 16.1 "traditional knowledge associated with genetic resources") utilized within their jurisdiction have been accessed in accordance with prior informed consent ("PIC") and that mutually agreed terms ("MAT") have been established as required by the domestic access and benefit-sharing legislation or regulatory requirements of the other Party", and if applicable the "approval and involvement of the indigenous and local communities" ("ILCs"). These articles of course cover only cases of utilization within the jurisdiction of a Party to the Protocol.

These articles are the legal basis for user countries to regulate cases of misappropriation of GR and TK associated with GR (TKaGR), accessed without observing the legislation of the providing country on PIC and MAT in force at the time of access of the resources. The pre-condition is that the provider country must

have enacted ABS legislation requiring PIC and MAT and ABS legislation related to TK (not extended to customary laws, community protocols and procedures of the ILCs). “In other words, the measures taken by the Party will have to support the verification of the existence of PIC and MAT but not the actual content of such terms or their enforcement” (Greiber et al., 2013, p.163). Parties have flexibility in deciding which kind of measures to adopt, as far as they are “appropriate, effective and proportionate”. Furthermore articles 15.2 and 16.2 prescribes that when a user does not observe such compliance measures adopted by the user’s country, the Party where utilization takes place should take “appropriate, effective and proportionate measures to address situations of non-compliance”. Parties again have flexibility in deciding which measures to adopt. It is therefore important to notice that in the absence of clear user measures adopted by a country where a non-compliance situation occurs, it would be impossible to enforce extraterritorially the remedies and sanctions of the provider country’s legislation (Chiarolla, 2011). Thus with regards to the enforceability of compliance measures taken by Parties, user countries should ideally provide for clear remedies and sanctions, otherwise compliance would be undermined. Therefore it is of paramount importance that user countries adopt clear compliance measures providing for remedies and sanctions for non-compliance cases, in order to guarantee ABS compliance to provider countries. Finally articles 15.3 and 16.3 of the Protocol prescribe that in cases of alleged violation, Parties should co-operate. This obligation implies for instance sharing investigations and exchanging information, but it cannot be read as including the issue of recognition of foreign judgements (Greiber et al., 2013).

Article 17 on monitoring the utilization of GR requires another active role of countries where genetic resources are used. However, the article does not apply to TK associated with GR. “To support compliance, each Party shall take measures, as appropriate to monitor and to enhance transparency about the utilization of genetic resources.” It introduces two new elements, i.e. checkpoints and certificates of compliance. A Party must nominate at least one entity that is responsible for monitoring the utilization of genetic resources. Each Party has discretion on which particular entity/ies to nominate as checkpoint/s. Such checkpoints would collect or receive “as appropriate” relevant information regarding PIC, the source of a genetic resource, the establishment of MAT and/or the utilization of a specific genetic resource. The checkpoint/s might have an active role in collecting information or a passive one limited to receiving them, the choice of which is discretionary to the Party, including the possibility to assign both roles (Greiber et al., 2013). However they must be “effective”.

Parties shall require users to provide to the checkpoints information related to the permit showing PIC from the providing country, the source of the GR, the establishment of MAT and/or the utilization of GR (NP, Article 17 (a)(ii). Such information, including the internationally recognized certificate of compliance (IRCC), when available and without prejudice to the protection of confidential information, has to be provided to the relevant national authorities, to the Party providing PIC and to the Access and Benefit-sharing Clearing House (ABS CH)

(NP, Article 17(a)(iii). This international obligation already creates a compulsory ABS flow of information from a user in a country Party to the Nagoya Protocol, to the provider country and to the ABS CH: this is already an important feature of a monitoring and tracking system (Chapter 4). A permit in accordance with Article 6 (Access to GR) and communicated to the Clearing House (NP, Article 14) constitutes an IRCC, that provides evidence that the GR which it covers has been accessed in accordance with PIC and that MAT, as required by the provider's national legislation, have been established. Article 17 also states that the certificate of compliance should at least contain the following information (when it is not confidential): issuing authority, date of issuance, provider, unique certificate identifier, user to whom PIC was granted, subject matter or GR covered by the permit, proof of MAT and PIC obtained and intended commercial and/or non-commercial use.

Moreover, as per article 15, Parties have to take "appropriate, effective and proportionate measures to address situations of non-compliance" by users with the above-mentioned obligation to provide information.

Article 17 furthermore requires Parties to take measures "encouraging users and providers of genetic resources to include provisions in mutually agreed terms to share information on the implementation of such terms, including through reporting requirements" (Article 17.1 (b)) and "encouraging the use of cost-effective communication tools and systems (NP, Article 17.1 (c)). As presented in Chapter 4 (Paragraph 4.3.3), it is of paramount importance for a tracking system to work to include clear reporting requirements in mutually agreed terms (MAT) standard clauses.

In October 2014, the Conference of Parties to the Protocol recognized "the crucial role that the Access and Benefit-sharing Clearing-house has in enabling information-sharing, and supporting legal certainty, clarity and transparency in the implementation of the Nagoya Protocol, in particular for accessing genetic resources and traditional knowledge associated with genetic resources, monitoring the utilization of genetic resources and facilitating compliance" (UNEP/CBD/NP/COP-MOP/1/L.8, p. 1). It welcomed "the progress made by the Executive Secretary and the experience gained during the implementation of the pilot phase and capacity-building activities for the Access and Benefit-sharing Clearing-house", and it decided "to establish an informal advisory committee in order to assist the Executive Secretary with the implementation of the Access and Benefit-sharing Clearing-house and to provide technical guidance with respect to the resolution of technical and practical issues arising from the ongoing development of the Access and Benefit-sharing Clearing-house" (UNEP/CBD/NP/COP-MOP/1/L.8, p. 2). In describing the modalities of operation of the ABS Clearing House the COP/MOP suggested to "design the ABS Clearing-house to be interoperable and facilitate the exchange of information with other databases and systems, in particular Parties' databases, as well as databases of other instruments and organisations" (UNEP/CBD/NP/COP-MOP/1/L.8, p. 3). This

is a crucial suggestion for the development of any monitoring and tracking system (see Paragraph 4.3.4).

Moreover, the use of unique identifiers generated through the ABS Clearing House is recommended to retrieve information on internationally recognized certificates of compliance. The system should "allow for a mechanism to amend or update information while preserving legal certainty, clarity and transparency, particularly in the case of a permit or its equivalent that constitutes an internationally recognized certificate of compliance" (UNEP/CBD/NP/COP-MOP/1/L.8, p. 3). The possibility to amend or update the information of the IRCC is fundamental for the monitoring and tracking system proposed in Chapter 4 (Paragraph 4.3.2).

The case of contractual breach of MAT terms is addressed by article 18 of the Nagoya Protocol, which completes the set of provisions covering "user country measures". MAT are determined through a civil law contract. "It is commonly understood that relationships of a contractual nature where private parties are involved fall in the domain of private international law when one party resides in a foreign country. They are usually not dealt with through a public international law instrument, such as the Nagoya Protocol, which is deemed to rule relationships between States" (Greiber et al., 2013, p. 184). However article 18 of the Protocol nonetheless encourages the parties to the contract (providers and users) that are agreeing on MAT, both related to GR and TK, to include provisions for dispute resolution in order to regulate a dispute in relation to the implementation of MAT. These provisions should indicate the competent jurisdiction; the applicable law; and/or alternative dispute resolution options. Discretion is left to the Parties on which options to adopt in the MAT, if any. It has been suggested that in order to avoid the contentious issue of recognition and enforcement of foreign judgements, the Parties may wish to choose the jurisdiction of the user for regulating disputes (Greiber et al., 2013). Article 18.2 imposes on Parties to ensure at the domestic level that if a dispute arises from MAT, recourse is available under its national legal system; while paragraph 3 prescribes to the Parties to take effective measures, as appropriate, regarding access to justice and the utilization of mechanisms regarding mutual recognition and enforcement of foreign judgements and arbitral awards.

These compliance articles (NP, Article 15-18) were seen by developing countries as the cornerstone of the Protocol (Greiber et al., 2013). They offer some innovative tools to grant users' compliance, even though most of the provisions leave to the Parties a great deal of flexibility on how to implement them, and they require Parties only to take those measures that are appropriate and proportionate. "However a certain 'performance requirement' is also established, as the measures finally taken have to be effective." (Greiber et al., 2013, p. 30).

Article 30 also deals with procedures and mechanisms to promote compliance with the Protocol, but leaves it up to the Conference of the Parties to consider and approve cooperative procedures to promote compliance and to address cases of non-compliance, intended as compliance with the NP and not as compliance

measures taken by the Parties and user compliance (as article 15-18 provide for). The Conference of the Parties serving as the meeting of the Parties to the Nagoya Protocol on Access and Benefit-sharing in October 2014 adopted “cooperative procedures and institutional mechanisms to promote compliance with the provisions of the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization and to address cases of non-compliance” (UNEP/CBD/NP/COP-MOP/1/L.11, p. 1). It then established and elected the Compliance Committee. The Committee will receive “any submissions relating to issues of compliance and non-compliance with the provisions of the Protocol from:

(a) Any Party with respect to itself;

(b) Any Party with respect to another Party;

(c) The Conference of the Parties serving as the meeting of the Parties to the Nagoya Protocol.” (UNEP/CBD/NP/COP-MOP/1/L.11, p. 4)

1.2 REGIONAL ABS LEGAL FRAMEWORK: EU ABS REGULATION

Genetic resources and associated traditional knowledge are of paramount importance for the EU biotechnology sector.

The European Union (“EU”), where significant biodiversity-based research and development activities are located, recognizes its responsibility in fostering respect for ABS requirements, as well as ensuring legal certainty in the conduct of these activities (Schally, 2012). While the role of Europe as a provider of genetic resources and/or traditional knowledge is a debatable matter, its position as a major user of global genetic resources is a settled fact (Coolsaet, forthcoming). A study considered in the elaboration of the initial proposal of the EU ABS Regulation underlined biodiversity-based activities in a variety of economic sectors in Europe, including academic research, pharmaceuticals, plant breeding, biotechnology and food and beverages (IEEP, 2012). Taking such facts into account, the EU adopted on 16 April 2014 the “Regulation of the European Parliament and of the Council on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union” (“EU ABS Regulation”) focusing mainly on user-measures.

The Regulation applies to genetic resources over which States exercise sovereign rights and to associated traditional knowledge that are accessed after the entry into force of the Nagoya Protocol (EU ABS Regulation, Article 2). The EU ABS Regulation does not regulate access to GR and TK within the EU: this is left to the Member States to regulate if they wish to do so. In this context, the main provision of the Regulation is its “obligation for users” (EU ABS Regulation, Article 4) which requires users to exercise ‘due-diligence’, with the aim of ensuring that genetic resources and associated traditional knowledge have been accessed and are

being utilized in accordance with regulatory requirements and mutually agreed terms, and that benefits are fairly and equitably shared upon MAT. Moreover, GR and TK associated with GR shall only be transferred and utilized in accordance with MAT if they are required by applicable legislation or regulatory requirements. Exercising due diligence has to be understood as seeking, keeping and transferring the 'internationally recognized certificate of compliance' and the information on the content of MAT to subsequent users. In case such a certificate does not exist, the Regulation lists a series of information and relevant documents to be sought, kept and transferred by users, including the date and place of initial access, the description of the resources, the source of access and the previous users, the relevant ABS-related rules, the access permit and the mutually agreed terms. If there were insufficient information or uncertainties about the legality of access and utilisation, "users shall obtain an access permit or its equivalent and establish mutually agreed terms, or discontinue utilisation" of the genetic resources or traditional knowledge (EU ABS Regulation, Article 4.5).

Due diligence would be monitored, with users required to make a declaration of due diligence at certain 'check points' (EU ABS Regulation, Article 7), and they have to submit the information of the IRCC or the minimum dataset in case the certificate is not available. Two are the checkpoints established by the EU ABS Regulation: "all recipients of research funding involving the utilization of genetic resources and traditional knowledge associated with genetic resources " and "the stage of final development of a product developed via the utilisation of genetic resources or traditional knowledge associated with such resources", therefore one downstream and one upstream in the value chain. In these two moments users have to declare that they have exercised due diligence in acquiring GR.

The competent authorities established under the Regulation have to transmit the information received by the users to the ABS Clearing House, to the European Commission (EC) and, "where appropriate" to the competent national authorities established according to the Nagoya Protocol. The competent authorities should cooperate with the ABS CH to ensure that the information is exchanged to facilitate the monitoring by the competent authorities of the compliance of users. The compulsory international flow of information established by the NP is strengthened by the EU ABS Regulation. Respect for confidentiality of commercial or industrial information is to be granted by the competent authorities by Article 7.5.

Controls to verify whether users comply with their obligations of due diligence and of monitoring user compliance are regulated by article 9 of the Regulation: EU Member States (competent authorities) are required to check on compliance, looking at measures taken by a user to exercise due diligence and relevant documentation and declarations (EU ABS Regulation, Article 9). These controls would be conducted in accordance with a periodically reviewed, risk-based plan, and they should be "effective, proportionate and dissuasive". Competent authorities will verify user compliance when they possess information regarding user's non-compliance, following a periodically reviewed plan, and/or through on on-the-spot checks and controls. Where "shortcomings have been detected, the competent

authority shall issue a notice of remedial action or measures to be taken by the user" (EU ABS Regulation, Article 9.6).

The due diligence approach presents an advantage in the fact that it provides for the flexibility required for measures in different sectors and situations, as stated in the Explanatory memorandum attached to the Regulation Proposal. Indeed, compliance measures apply to all users, while allowing consideration of different types of actors, sectors and other relevant factors in determining what works best in different circumstances (EU ABS Regulation, Preamble). Moreover, in the EU Regulation context best practices could help identify due diligence measures that are particularly suitable for achieving compliance with ABS, with legal certainty and lower costs (EU ABS Regulation, Preamble). For this reason, the Regulation establishes the possibility of the official recognition of best practices: associations of users and other interested parties will be able to request recognition by the European Commission for a specific combination of procedures, tools or mechanisms as best practice for due diligence requirements (EU ABS Regulation, Article 8).

The EU ABS Regulation prescribes for additional measures to support the development and adoption of best practices: article 13 calls for encouraging the development of sectorial codes of conduct, model contractual clauses, guidelines and best practices, particularly where they would benefit academic researchers and small and medium-sized enterprises.

Besides the user measures, the Regulation leaves important responsibility to non-state actors, through self-regulation and voluntary provisions. As such, the Regulation aims to establish a list of registered ex-situ collections which restrict "the supply of samples of genetic resources to third persons with documentation providing evidence of legal access" (EU ABS Regulation, Preamble, Recital 28). Users accessing genetic resources from a registered collection will be considered to have exercised due diligence, a measure which is likely to lower the administrative burden.

Article 11 of the Regulation calls upon Member States to establish rules on penalties applicable to infringements of the obligations related to due diligence and to monitoring user compliance (Articles 4 and 7 of the EU ABS Regulation): these penalties shall be "effective, proportionate and dissuasive".

1.3 BRAZILIAN ABS LEGISLATION

Brazil was one of the first mega diverse countries to enact national legislation on ABS, aiming at implementing the CBD at the national level. It did so through Provisional Act 2186-16/2001 (Provisional Act), which aimed to regulate access to GR, to associated TK, trigger benefit sharing derived from their use, and the transfer of technology for the conservation and use of biological diversity. The

Genetic Patrimony Management Council (CGEN) is responsible for GR management policies.

The Provisional Act is being replaced by the new draft ABS legislation which is still waiting for the adoption by the National Congress. An analysis of the current applicable Brazilian ABS legislation (Provisional Act) goes beyond the scope of the present study. For the purpose of the present study it is important to highlight that, as it will be shown in chapter 3, Brazilian pharmaceutical companies are today avoiding to use Brazilian biodiversity in their research and development pipeline due to the highly bureaucratic procedure of the authorization within the Provisional Act and the legal uncertainty surrounding the consequences of such authorization on their business model and research and development efforts. The new draft ABS legislation is likely to improve this situation.

The review of the current national ABS legislation started already in 2003: with the new draft the ABS legislation in Brazil is shifting its governance model from an authorization model to a declaration one, with the exception of foreign actors not associated with any Brazilian one for which the authorization procedure is still in place.

1.3.1 DEFINITIONS

The core concepts of the new legislation are the definitions of:

- genetic heritage - genetic information of plant species, animal, microbial or otherwise, including substances derived from the metabolism of these living beings, found in situ, or maintained in ex situ conditions.

- access to genetic heritage as research and development performed on sample of genetic heritage (article 2.VIII)

- access to associated traditional knowledge as research and development performed on traditional knowledge associated with genetic resources that enables or facilitate access to genetic resources, although obtained from secondary sources such as trade fairs, publications, inventories, films, papers, records and other forms of systematization and record associated traditional knowledge (article 2.IX)

- access register of genetic resources or associated traditional knowledge as mandatory declaratory instrument of access activities or shipment of genetic heritage or associated traditional knowledge (article 2.XII)

- notification of product or process as declaratory instrument that predates the beginning of the activity of economic exploitation of the finished product or process arising out of access to genetic heritage or associated traditional knowledge, in which the user declares the compliance with the requirements of this Act and indicates the type of benefit sharing when applicable, to be established in the benefit-sharing agreement (article 2.XIX)

- regular access certificate as administrative act by which the competent body declares that access to genetic resources and associated traditional knowledge fulfilled the requirements of this Act (article 2.XII)

1.3.2 ACCESS PROCEDURES

Article 3 prescribes that product or process arising out of access to genetic heritage (GH) existing in the country or traditional knowledge associated with them, will only be made upon registration, authorization or notification, and will be undergoing inspection, restrictions and benefit-sharing under the terms and conditions established in this Act and its rules.

Prior informed consent and the authorization to access GH and associated TK have to be sought only in two cases:

- When access is to GH associated with TK: article 9 prescribes that access to traditional knowledge associated with an identifiable source is subject to obtaining the consent of the local or indigenous community detaining the TK, then the user must present this consent when registering the intended access and asking for the prior informed consent to CGEN Moreover in this case article 25 prescribes for the obligation to negotiate mutually agreed terms with the local or indigenous community on a fair and equitable benefit sharing when the finished product is derived from TK associated with an identifiable source.

    - When access is sought by foreign entities not associated with any national institution

Art. 13 prescribes that prior authorization should be asked for the following activities:

- Access to genetic heritage and associated traditional knowledge by individual, legal headquartered registered abroad not associated with national institution;
- Shipment of samples of genetic heritage abroad with the purpose of access by overseas institution not associated with national institution.
- For the purposes of this Act, any traditional knowledge associated to genetic heritage shall be considered of collective nature, even if it is held only by a single individual belonging to an indigenous people group or traditional community.
- National users seeking access to GH (not associated with any TK) merely have to fulfil the requirements of a lighter procedure, i.e. the registration. Article 12 prescribes for the registration of the following activities:
- Access to genetic heritage and associated traditional knowledge within the country conducted by national, both public or private legal person;

- Access to genetic heritage and associated traditional knowledge by individual, legal headquartered registered abroad but associated with national institution;
- Access to genetic heritage and associated traditional knowledge undertaken abroad by national, both public or private legal person;
- The shipment of sample containing genetic heritage to national corporations, public or private, to provide services abroad as part of research or development.

The registration should be done prior to the filling of any applications of any intellectual property right, the dissemination of results, final or partial, in scientific media and before commercialization of intermediate products.

Article 15 prescribes that when the economic exploitation of the finished product starts a notification to CGEN has to be submitted before marketing the product, and within a year from the date of notification a benefit sharing agreement has to be signed.

1.3.3 BENEFIT-SHARING

Article 18 prescribes that benefits from the economic exploitation of the finished product arising from access to genetic resources and associated traditional knowledge, although produced outside the country, in which the component of the genetic heritage or traditional knowledge is a major element of adding value to the product, shall be shared in a fair and equitable manner. Exclusively the product manufacturer, regardless of who performed earlier access, will be subject to sharing of benefits. Finally when a single finished product is the result of different accesses, they will not be considered cumulatively for the calculation of the distribution of benefits.

The micro-enterprises, small and medium enterprises (SMEs), as provided in the Supplementary Law No. 123 of December 14, 2006, will be exempt from the benefit sharing requirements under the proposed regulation.

Article 19 prescribes that benefit sharing may be monetary or non monetary, at the discretion of the user. If monetary, 1% of the annual net revenue from economic exploitation has to be paid. Article 21 prescribes for exceptions that could be granted to individual sectors to safeguard their competitiveness through sectoral agreement that can set up a smaller percentage of monetary benefit sharing. In case non-monetary benefit sharing, the distribution of benefits should be equivalent to at least 75% of the predicted monetary amount (article 22).

Article 31 establishes the National Fund for Benefit Sharing with the goal of enhancing the conservation of genetic resources and associated traditional knowledge and promoting their sustainable use.

1.3.4 COMPETENCES

The main competent authority designated by the Brazilian law is the Genetic Patrimony Management Council (CGEN). For instance, Article 6 gives to CGEN the power to:

- Establish technical standards and criteria for the creation of database for recording information about genetic heritage and associated traditional knowledge;
- Monitor, in conjunction with federal agencies, or by agreement with other institutions, the activities of:
- Access and shipment of samples containing the genetic heritage;
- Access to associated traditional knowledge;

CGEN shall furthermore decide on:

a) The authorization

b) The accreditation of a national institution as trustee of samples contains the genetic heritage;

c) The accreditation of a national institution to be responsible for creating and maintenance of the database referred to in subsection XI.

Moreover, the CGEN creates and maintains a database of:

a) The records of access to genetic heritage or associated traditional knowledge;

b) The authorization of access to genetic heritage or associated traditional knowledge;

c) Instruments and terms of material transfer;

d) The ex situ collections of accredited trusted institutions as depositories;

e) Notifications of product and process;

f) The benefit-sharing agreements;

g) The certificates of regular access.

Its role is therefore more than central in the administration of the proposed ABS regime, and shall therefore remain at the centre stage in relevant compliance and tracking efforts.

1.3.5 CONCLUSIONS

The new Brazilian draft legislation is based on a lighter bureaucracy, at least for national users (and for foreign users associated with a national user) who seek access to GR only (and not their associated TK), as they will have only to register when doing access within the meaning of the new draft legislation, that is to say when doing research and development. This change establishes a significantly

less burdensome procedure for national companies (pharmaceutical and others) which seek to use Brazilian biodiversity within their pipelines. No authorization needs to be obtained before the start of research activities, and only a simple online registration has to be filled in during such early stages. No complex negotiation has to be undertaken with the provider (usually the land owner), and no bargain on benefit sharing has to be negotiated without precise knowledge on the economic value of the research and development activities that entities are embarking upon. This change is likely to improve the situation of the Brazilian pharmaceutical market which depends by 70% on imports, by supporting the national industry which avoids using Brazilian genetic resources within its pipelines of research and development due to the high bureaucracy and the legal uncertainties that have been created by the application of the Provisional Act (See Chapter 3).

2 CODES OF CONDUCT, GUIDELINES, BEST PRACTICES AND PRIVATE STANDARDS ON ABS

Throughout the process of implementing the Convention on Biological Diversity and the Nagoya Protocol, it became clear that effective implementation could not only rely on government measures. Under the contractual approach established by the CBD, users of genetic resources are as a result responsible for jointly establishing and implementing the conditions for access to GR and the arrangements for sharing the benefits resulting from the resources' use. Moreover, users of genetic resources, their suppliers, and their clients need to gather and provide information regarding access permits and benefit sharing agreements, monitor and evaluate fulfilment of related requirements, as well as take measures to prevent illegal use, a need that was already held up in Article 16d of the Bonn Guidelines adopted by the conference of the Parties of the CBD in 2002. As a result, the effective implementation of international, regional and national ABS regimes cannot rely solely on top-down regulatory efforts, but also requires the active involvement of the users of genetic resources, including the scientific community and the private sector (Monagle, 2013). That is why several research and industrial sectors have developed self-regulating and voluntary codes of conduct, guidelines, best practices on ABS, going as far as adopting model contractual clauses in many cases. Most of them have been developed between the adoption of the CBD in 1992 and the adoption of the Nagoya Protocol in 2010.

Pursuant to article 19 and 20 of the Nagoya Protocol, each Contracting Party agrees to encourage, as appropriate, the development, update and use of sectoral and cross-sectoral model contractual clauses for mutually agreed terms, as well as for voluntary codes of conduct, guidelines and best practices and/or standards in relation to access and benefit sharing. The Protocol's main implications for model contractual clauses result in particular from its provisions on access to genetic resources, benefit sharing, special considerations, traditional knowledge, monitoring, compliance with mutually agreed terms, capacity, technology transfer, collaboration and cooperation. The clauses that are relevant for the present study concern more particularly those that have implications for the monitoring and tracking of accessed GR and associated TK. These will be of inspiration to shape the monitoring and tracking system in chapter 4.

"Codes of conduct, guidelines and best practices may support the legal arrangements that underpin ABS, and might be relevant to the process of negotiation the content of agreements, or both. In some cases, such support tools might be directly referred to in ABS agreements, and so become legally relevant to the obligations of contracting parties under that agreement. Compliance with such codes may also be encouraged in other ways, such as through becoming the condition of a research grant for example" (UNEP/CBD/ICNP/3/INF/2, p. 12). The wide range of available codes is also explained by the fact that different types of GR are used by different types of users, for different purposes, across a range of sectors (UNEP/CBD/ICNP/3/INF/2). However, the sector in which the code of

conduct/model agreement is to be applied tends to be only one factor among several responsible for differentiation between the models available. Indeed, differences of approach between model contracts tend also to include issues such as whether the research is expected to be commercial or non-commercial in nature, sometimes even more prominently than the specific sector of application.

This chapter will analyse the codes of conducts, guidelines, best practices and private standards (as a special category of best practices) that are more relevant for the pharmaceutical sector, considering that the illustrative focus of this study is the pharmaceutical sector in Brazil (which will be briefly illustrated in Chapter 3). Having regards to the fact that the Brazilian pharmaceutical sector may be mainly considered a user of plant and microbial GRs, including sometimes associated traditional knowledge, together with user synthetizing technologies, the present analysis will focus on the following codes of conduct:

- Micro-Organisms Sustainable Use and Access Regulation International Code of Conduct (MOSAICC), developed in 1999, revised in 2009, and being currently revised in light of the Nagoya Protocol and turned into the Transparent User Friendly System of Transfer for Science and Technology (TRUST) - implementing the Nagoya Protocol in microbiology -Guidelines ;
- International Plant Exchange Network (IPEN) Code of Conduct for botanic gardens governing the acquisition, maintenance and supply of living plant material, developed in 2001;
- Consortium of European Taxonomic Facilities (CETAF) Code of Conduct and Best Practice for Access and Benefit-Sharing, developed in 2012
- Global Genome Biodiversity Network (GGBN) Code of Conduct, Best Practices for Access and Benefit-sharing, which is still under drafting process and might still be subject to change;
- NIEMA “The Network of International Exchange of Microbes in Asia”, proposing a legitimate and streamlined way of transferring and utilizing microbial resources in line with the Nagoya Protocol, which is under development by the Asian Consortium for the Conservation and Sustainable Use of Microbial Resources (ACM), established in 2004.
- Guidelines for BIO Members engaging in Bioprospecting, developed in 2005 by the Members of the Biotechnology Industry Organization;
- Guidelines for International Federation of Pharmaceutical Manufacturers and Associations Members (IFPMA) on Access to Genetic Resources and Equitable Sharing of Benefits Arising out of their Utilization, developed in 2006 and revised in 2011 in light of the Nagoya Protocol;
- Association of European Self-Medication Industry (AESGP) Proposal for a Best Practice Guide of the European Herbal Industry in the framework of the implementation of the Nagoya Protocol, drafted in 2012-2013.

While the first five documents have been drafted within basic research communities, (even though these communities might also go through occasional commercial research applications), the last three have rather been drafted by industrial associations, with a clear focus on commercialization potential. They have all in common the perspective of GR users, and most of them recognize the importance of scientific research on GR and the important benefit to society as a whole that arise from such research. Some of them also stress the importance of the CBD's (and the Nagoya Protocol's) provisions requiring States to facilitate access for basic research (IFPMA - MOSAICC/TRUST).

The aim of an ABS code of conduct is a triple one. First it is a political recognition and support of the international ABS framework by the institution drafting the code. Second, it aims at granting compliance with ABS principle by raising awareness among the practitioners working within a group of researchers or industries. The third goal relates to the desire to minimize bureaucracy and facilitate access and exchange of resources by the creation of a group within which exchanges are governed by the same standardized rules, in some cases establishing what can be called a "network of compliance", as shall be further touched upon below. The first part of these codes is usually dedicated to the endorsement by the institution of the Convention on Biological Diversity and its principles (and the Nagoya Protocol in case the code is subsequent the Protocol). Then they usually proceed to illustrate the steps that their institution, employees, and/or researchers should go through before accessing any GR, whether this entails obtaining prior informed consent (PIC) from the competent authority and from the holder of traditional knowledge (if relevant) when this is required by the law of the Provider Country, or involve the negotiation of mutually agreed terms (MAT) on the use of the GR, the transfer to third parties, the monetary and non-monetary benefit-sharing, the monitoring of the utilization of the acquired GR, and perhaps addresses issues regarding monitoring and reporting requirements, capacity building and technology transfer. The institutions that endorse a code of conduct generally reaffirm the principle according to which they will use and transfer the accessed GR in accordance with the terms of use given by the providing country. The sharing of scientific information generated through the conduct of research upon the accessed GR is a common element to all studied codes. However, guidelines having a clearer industry perspective (such as BIO) underlines that this should be done in conformity with standard industry practices regarding timing and conditions of public disclosure, in order to preserve options for procurement of patents or preservation of confidentiality. Some characteristics of the different codes of conduct, guidelines and best practices are worth being underlined, as they could be of inspiration for the establishment of an efficient system of monitoring, and tracking of accessed GR.

A stand-alone category of best practices is also worth mentioning: the private standards (Oliva, 2012) that are developed by actors concerned with biodiversity-based activities through a 'bottom-up' approach. These standards could help interpret legal requirements for a more practical and effective implementation of the

ABS obligations (Oliva, 2012), and will therefore also be analysed at the end of the chapter.

2.1 BASIC RESEARCH CODES OF CONDUCTS

2.1.1 INTRODUCTION TO EX SITU COLLECTIONS

Ex situ conservation is defined by Article 2 of the CBD as “the conservation of components of biological diversity outside of their natural habitats”. Ex situ collections are collections of genetic resources held for example in gene banks, botanical gardens, arboreta, zoos, in vitro storage and DNA storage. Most research undertaken at the level of ex situ collections, if not all, is of a non-commercial nature, aimed at improving understanding of genetic diversity and how to best conserve it (Greiber et al., 2013). Moreover, most of the genetic resources collected ex situ were accessed before the entry into force of the CBD in biodiversity-rich countries. The Bonn Guidelines prescribes that for ex situ collections, prior informed consent should be obtained from the competent national authority(ies) and/or the body governing the ex situ collection concerned as appropriate. It is important to notice that some ex situ collections, such as botanical garden and herbaria consider the whole of their collection as falling under the obligations of the CBD, regardless of the date of the first collection of the resources, due to ethical and pragmatic reasons (IPEN, GGBN also suggests this).

The Nagoya Protocol encourages Parties to develop and use voluntarily codes of conduct, guidelines and best practices in relation to ABS, and the Open-ended Ad Hoc Intergovernmental Committee (ICNP) for the Nagoya Protocol on ABS, acting as an interim governing body for the Nagoya Protocol until the first meeting of the Parties to the Protocol takes place, has been gathering and discussing recent updates of such documents. Moreover, as seen in Chapter 1 the EU Regulation has recognized the culture collections, through the creation of a register of collections established and maintained by the European Commission.

The ex situ collections are therefore important actors in the field of ABS. Moreover, given their role in conserving biodiversity and ensuring access for scientific research purposes and their usually publicly funded origin, they provide to the society fundamental services. Their advanced raising awareness activities in the field of ABS is of paramount importance.

The duty of ex situ collections, whether microbial, plant, DNA or taxonomic collections, is to provide for high quality reliable raw material for research and innovation, fostering cumulative research. They aim at establishing a system that in one hand provides for easy circulation of GR and in the other hand monitors the distribution and the utilization of such GR in order to be ABS compliant. Collections also promote and respect intellectual property rights of all stakeholders and they

operate in compliance with safety and security rules, especially when shipping materials.

2.1.2 NETWORKS OF COMPLIANCE

The five codes of conducts orientated towards basic research (IPEN, MOSAICC/TRUST, CETAF, GGBN and NIEMA) are much more comprehensive and detailed. They all impose to their "memberships" as a first step to acquire only biological material that has been legally accessed, trying therefore to establish a "network of compliance" where the materials inside the network would unequivocally be ABS compliant, and where materials are exchanged according to a standardized and simplified procedure. The GGBN Best Practices on ABS also refers to the principle of due diligence, requiring to the institutions to ensure that they do not acquire biological material without being confident that they can retain the material legally. They all restrict the scope to the use of biological material only for non-commercial purposes, leaving the commercial use to bilateral negotiation between the provider country and the user. They also all require that members negotiating PIC and MAT should be clear about the purposes for which the material will be used. Finally, they all prescribe to utilize the GR and their derivatives according to the terms and conditions under which they were accessed or otherwise acquired, imposing a re-negotiation if and when these terms ought to be modified.

The CETAF and the GGBN are very similar as the latter has been shaped on the former, and considering that the two groups have in part the very same membership, the GGBN having been created by excluding some of the non-genomic aspects of the CETAF. Both institutions have developed sets of three documents: the Code of Conduct is the general principles to which the members adhere, written to provide a clear overview of those principles; the Best Practice provides details on how the Code of Conduct should be put into practice, and thus goes into more detail; and the Use Statement is a tool written to facilitate the attainment of PIC, clarifying to providers the intentions of the members in the use of accessed material.

The IPEN Code of Conduct identifies the Consortium of Botanic Gardens in the sense that by registering to the Consortium a botanic garden declares (in written) the adoption of the Code of Conduct. The membership is then eventually accepted upon the decision of the IPEN National Node Network. On the same line, the basis of the NIEMA is the registration of a Microbial Resources Center (MRCs) that declares to adopt the NIEMA code of conduct as a common policy. This strongly recognized membership contributes to the creation of worldwide confidence in the work of botanical gardens on the one hand, and of Microbial Resources Centers on the other. This feature is fundamental in terms of trust and reliability for the users that are accessing GR through ex situ collections member to these networks, thus it is an important component to be strengthened in view of a monitoring and

tracking system: acquisition of GR from such networks should be encouraged and/or a reward could be offered in case of such a behaviors (See Chapter 4).

IPEN distinguishes between two types of documentation: the first, so-called 'maximum documentation' has to be kept by the first botanical garden introducing an accession (plant material) into the IPEN network. In this documentation sheet, all relevant information about the plant accession is recorded, such as taxonomic data, type of material, source, permits related to the acquisition and any conditions or terms of the country of origin. This first garden also has to provide the accession with the "IPEN number", which will follow the accession and all its descendants through all exchanges within IPEN as the so-called 'minimum documentation' (UNEP/CBD/ICNP/3/INF/2). When receiving material from another member of the IPEN it is indeed sufficient to document the information listed in the minimum set of data. Therefore plant material is exchanged between IPEN members under the same terms under which it was acquired. According to the same principle, if transfer is not prohibited under the original PIC and MAT, specimens may be freely transferred between signatories to the IPEN Code of Conduct and who have adopted its Best Practice. By doing so, the IPEN creates a network of facilitated exchange and ABS compliance tracking. However, it is important to highlight that it is still voluntarily and not legally binding, and provides for no sanctions in case of non-compliance, therefore it remains difficult to guarantee the effectiveness of this compliance system.

The TRUST also focuses on the creation of a "network of compliance" by providing a framework through which the in situ origin of the material is recorded via the initial PIC of the provider country (which must be obtained prior to accessing the resources, unless otherwise determined by the national legislation of the provider); the deposit of the material into an ex situ collection is registered under the Material Accession Agreement (MAA); and the transfer of material between ex situ collection are monitored under the Material Transfer Agreement (MTA). These are models agreements with standardized definitions and clauses that help microbiologists to be compliant with ABS requirements. They require that every microbial genetic resource "entering" a collection is covered by a PIC obtained at the time of its isolation from in situ conditions, or after corrective administrative action, and that every microbial genetic resource having entered a collection with the appropriate initial PIC may be distributed, accompanied by the original PIC, without any additional PIC procedure set by the country of origin or the country of use. Like the TRUST, the NIEMA covers the registration of microbial strains into the NIEMA system, the exchange of the microbial strains between NIEMA MRCs and the distribution of the NIEMA strains from NIEMA MRCs to third parties only for non-commercial research purposes.

The IPEN Code encourages treating all plant materials as if acquired after the CBD came into effect, specifying anyway that no responsibility is accepted for retroactive benefit-sharing claims. The CETAF goes even further in encouraging institutions wishing to commercialize GR collected before the CBD came into force to share benefits fairly and equitably. The GGBN Best Practice on ABS leave the door open

for members to apply the practices to materials accessed before the CBD entered into force.

The most recent codes of conduct took into account the recent development of genomics technologies also in the procedural parts of the codes: for example the Statement of Use of Biological Material of the GGBN and of the CETAF both clarify that the materials will be used both in facilities managed or owned by the institutors accessing the material and in facilities owned or managed by others but mandated for specific purposes, as for example external DNA sequencing facilities. In the last case, if any commercial sequencing facility to which samples are sent as part of a research retains sequence data, the GGBN Best Practice clarifies that a contract excluding utilization not in compliance with the terms and conditions under which the biological resources were acquired should be agreed prior to sequencing.

2.1.3 TRACKING AND MONITORING – DATA MANAGEMENT SYSTEM

All the basic research codes of conduct contain interesting clauses related to monitoring, tracking and data management as a fundamental component of their ABS compliance system. These clauses prescribe that through the different steps registering the movement of GR/samples, certain information shall be recorded and transferred with the sample. This information asked to the depositor in a collection, being it microbial, plant or genomics, usually includes the minimum dataset prescribed by the Nagoya Protocol. The record of such information and above all the link between them and the deposited material, granted by the use of unique identifiers that helps to retrieve the necessary minimal information, are the core features of a viable tracking system.

The IPEN prescribes that the gardens have to use a database or record system that tracks all relevant data as plant material comes in and out of the garden, and it should distinguish between material suitable for the IPEN exchange and not suitable materials. The code also refers to international standards on data exchange and taxonomic databases and to the use of the IPEN numbers that remain connected with the material and its derivatives through all generations to come: with the help of this number it is possible to trace back where and under which conditions the plant material entered the IPEN. The number consists of four elements indicating the country of origin, restrictions of transfer, garden code, and identification number.

As far as curation is concerned, the GGBN Code of Conduct and Best Practice imposes to record all the information that may be required for reporting to a Checkpoint when the Nagoya Protocol comes into force, i.e. the description of the GR; the date and place of access to the GR and the legal permits (PIC, MAT etc..), and in addition to those, information on the utilization of the GR, the transfer to third parties (permanently or on loan) and the terms and condition of these transfers; and to record when the consumption of the samples is reached. According to the CETAF and the GGBN set of documents, the institution should implement an appropriate data management system allowing tracking the origin of any sample

(and provide any users with the information on terms of use) and trace the biological material that entered the collections. It should provide a mean to discover rapidly what legal requirements and restrictions are associated with the specimens: this might imply the adoption of unique identifiers ("as far as possible or required by the EU Regulation") that allow tracking of specimens, especially for processed DNA samples. The institutions should have clear policies for how to handle inappropriate utilization. The CETAF furthermore imposes to keep permanent record of any TK known to be in their collections. According to the CETAF and GGBN set of documents institutions may find it helpful to manage all required infranational, national and international legal documentation under the same policy umbrella; by doing this they will be able to use common database solutions and provide more effective staff training.

The GGBN and the CETAF set of documents impose that publications (including deposits to databases such as GenBank) resulting from the utilization of GR should ideally include an identifier of the permit or other legal agreements regulating the terms of use. Furthermore, they call for institutions to develop internal policies on collection audit to monitor if the institution is effectively managing its ABS documentation, complying with associated international and contractual agreements, and associated processes and to determine if improvements are required or possible.

According to the CETAF and the GGBN, the DNA sequence data will be deposited in publicly databases, such as GenBank, and the GGBN Statement of Use adds that only "where possible, referenced to the respective biological specimens store at the institution." This is probably due to technical barriers in ensuring that such link is maintained, but for future implementation of the Nagoya Protocol, public repositories will have to make sure that this link is maintained. According to the CETAF and the GGBN set of documents the institutions have to make their collection as accessible as possible to its direct scientific counterpart and to the wider community: the data, including the place and date of access. In the WFCC guidelines, it is pointed out that collections should publish, online or in printed form, catalogues to disseminate information of strains to promote scientific and industrial usage of holdings. However, according to the statistics, only one-sixth of collections registered in CCINFO have an online catalogue, which greatly hinders the visibility and hence the accessibility of strains. The World Data Centre for Microorganisms has constructed a data management system and a global catalogue to help organize, unveil and explore the data resources of its member collections. Such capacity building opportunities should be looked at (See Paragraph 4.3.1)

As for TK, the CETAF Use Statement clarifies that knowledge found in the public domain may be used in research, while for TK of which the holder is known, the institution will, as far a practicable and reasonable, store it in a way that it is not made available to third parties without PIC and MAT from such holder.

The tracking system of the TRUST and the GCM

The most advanced code of conduct in terms of monitoring and tracking is the TRUST of the WFCC. It is the combination of technical measures developed initially for scientific purposes and then used to manage access and use of microbial materials; and legal measures to manage private law contractual arrangements to describe rights and duties of ABS stakeholders. It is based on a strong cooperation between lawyers and life scientists.

The core of the tracking system for microbial GR within the TRUST is the use of global unique identifier (GUID). Once the PIC is granted by a providing country to access in situ GR, this is recorded at the ABS Clearing House and it becomes the Internally Recognized Certificate of Compliance: at this moment an IRCC unique identifier is generated attached to the biological item. At this step however the unique identifier is given to the ecological sample (such as soil for example), which can in fact contain many microbial GRs and a pure culture of one microbial strain. The issuance of a global unique identifier related to one pure culture of one microorganism is always made at the time of the deposit in an ex situ long-term conservation facility/culture collection. Practically, at the very first stage of access to in situ MGR, the samples are often not yet identified nor characterised. Therefore a PIC can merely refer to sampling aiming at particular kind of microorganisms. In other words, any authorization, including a PIC, cannot refer at this stage to a particular well-identified item. To tag a well-defined microbiological item is possible only after identification and characterization processes, which can be relatively simple or require extensive analysis. Thus, at this very first stage of "access", an internationally recognized certificate of compliance as described in article 17 of the Nagoya Protocol, or a unique identifier, or generally speaking any kind of tag, cannot yet be issued per single microbial GR.

It is the Global Catalogue of Microorganisms (see below) that makes the distinction between the ecological sample and the different microbial GR therein contained, by issuing the Global Unique Identifier after undertaking scientific analysis of the sample. The accession form, which is the document through which a microbial GR is registered in a collection (through which the collection accesses the GR) is adapted to the need of each collection and it is specific to the kind of material, as necessary information for one kind of microorganisms may not be relevant for another and vice versa. Therefore this document requires the registration of the essential information, in the minimum dataset (PIC, place and date of sampling, name of collector, substrate and collection reference); together with the scientific and technical data specific to the type of material. This specific information set depends on scientific knowledge therefore they are given through scientific analysis. This option of assigning a real global unique identifier is an interesting one in the view of the proposed monitoring and tracking system (See Paragraph 4.3.2).

The WFCC has developed a pioneering database system, the WFCC Global Catalogue of Microorganisms (GCM), by registering its members through a unique acronym and numerical identifier in its official directory. It is expected to be a robust, reliable and user-friendly system to help culture collections catalogue their

microbiological resources, to manage, disseminate and share the information related to their holdings. It also provides a uniform interface for the scientific and industrial communities to access the comprehensive microbial resource information. This system is managed by the World Data Centre for Micro-organisms (WDCM). Through the support of the GCM programme culture collections can get their data digitalized and accessible online. As already underlined this is an important capacity building opportunity given to culture collections, and it should be promoted by the Brazilian authorities.

GCM is a database that integrates information retrieved from other sources (other public repositories) connecting the strain catalogue information with corresponding nucleotide and protein sequences, as well as genome sequences and reference citations, setting up therefore a comprehensive database, analysis and visualization system for microbial resources. Combining the WDCM system and the use of electronic markers of the GUIDs, the GCM set up a robust system to organize transfers of (micro) biological items, tracking the flow of resources and related information. The CGM facilitates the application of ABS since it provides users with the ability to trace the possession, location, transmission and use of uniquely-identified microbial strains, including country of origin, existence of PIC and MAT, the creation of derived patents and all associated scientific publications. The current version of GCM already includes more than 60 collections from more than 30 countries and information on nearly 290.000 strains from 41.000 species.

The flow of information of the GCM is being connected to the ABS Clearing House through the link between the IRCC of the ABS CH and the GCM.

Another feature of a tracking system is the monitoring of the distribution and utilization of the GR. In regard to this aspect, the TRUST proposes the use of a MTA excluding further distribution to third parties (as a default option) in order to limit indefinite distribution, and to shorten the chain of distribution along which the monitoring of the transfer of GR may be lost. This also ensures that microbial genetic resources keep their original quality and characteristics. However, the MTA could allow transfer to third parties in case of “legitimate exchange” in the cases when:

- The GR is transferred to a recipient that is a culture collection
- Both recipient and provider are culture collections
- The GR is transferred between people working in the same research group.

Therefore when transferring to a recipient that is not a culture collection the non transfer to third parties option will be applicable. In case a third party requiring a strain that is subject to this, the code of conduct does not give to the culture collection any intermediary role between the third party and the provider country to which the third party needs to ask for the strain. The default option prohibiting transfer to third parties together with the concept of legitimate exchange among certain users is being considered in Chapter 4 (Paragraph 4.3.3) by the proposed monitoring and tracking system.

The TRUST recommends to microbiologists to work with “registered sources” as defined by the EU ABS Regulation, and if this is not possible, they have to ask to the collection the minimum information, such as country of origin or a reference that can lead to the PIC documentation. When the origin of the GR is not know, the source (the depositor) must be documented. The code of conduct prescribes also for a regularization procedure for ex situ GR that have been acquired in situ without PIC.

As far as capacity building to support the implementation of monitoring and tracking is concerned, the TRUST comprises a component of cooperative structure wherein culture collections make use of the latest ICT technology (see GCM mentioned above) to develop the necessary identification and tracking system, primarily for scientific purposes but also for any other bona fide ends; and conduct and facilitate research in genomics and functional genomics, thus develop capacities of storage and processing of genomic, transcriptomic and metabolomic information. These compiled data improve definite characterization of microbial resources and they implement the Nagoya Protocol provisions on technology transfer.

These innovative developments made in the microbiological field can be adapted to other fields of research, also enhancing interdisciplinary study of biological diversity. They are aiming at providing a cost-efficient, simple, fast and multiple users - multiple purposes global system.

2.1.4 TRAINING OF INTERNAL STAFF

The CETAF Best Practices on ABS focuses on training of internal staff in implementing the ABS policy, in keeping record and in being aware of the permission required prior to undertaking fieldwork.

The CETAF and GGBN codes of conduct impose the use of agreements to acquire biological material and to acquire TK associated with GR, and also prohibit employees from entering into agreements as individual or as institutional representatives without consultation with the institutional officials responsible for ABS. Moreover the GGBN Best Practices on ABS stress that the institution should draw up guidelines to assist staff in indicating clear rules on who is authorized to sign any agreement or to accept material in the name of the institution. These two clauses guarantee more legal certainty. The GGBN Best Practices is the only document underlining that institutions and staff should be aware, when contacting the National Competent Authority that other offices or authorities might need to be contacted as well, depending on the Provider country’s legislation.

2.1.5 SHARE OF SCIENTIFIC RESULTS AND DATA

Given the not-for-profit nature of the work of the GGBN Participating Institutions, the GGBN code of conduct focuses on non-monetary benefit sharing, and especially on the scientific partnerships and collaborations and the share of

scientific data and results openly in the public domain. However this particular openness of the data originated from GR should be probably object of negotiation with the Provider country. The critical issue of how public repositories (open access databases such as the genomics ones) can guarantee that the rights of the provider countries' are safeguarded in cases where restriction on the use of downstream data is attached has just started being discussed by practitioners and has no answer yet.

2.2 INDUSTRY CODES OF CONDUCT, GUIDELINES AND BEST PRACTICES

Within the industries' codes of conduct the BIO Guidelines is rather progressive. It prescribes not to accept samples of GR from a third party that is not able to provide evidence that it has obtained such samples in compliance with obligation of PIC, and conditions governing use that are applicable to the samples. This would be a first step to make the sector ABS compliant.

The IFPMA Guidelines contain a paragraph on "Enabling Steps by Government" comprising of the commitment for governments to enter into good faith negotiations as to the terms of access and benefit sharing contracts with commercial entities. No mention of the same good faith the industries should enter into negotiations with. This part also recommends the National Focal Point to establish databases recording the existence of GR and its uses.

Interestingly, the BIO Guidelines also impose to members to seek patents only on inventions that arise from the use or study of GR that are claimed in a manner clearly distinguishable from the form in which the GR have been provided by the Providing Party. Moreover, the BIO document has special consideration for the conservation and sustainable use of biological diversity, encouraging members to take reasonable steps to prevent harm to the local environment.

Some of the codes of conduct underline the peculiarities of the sector and its value chain, such as for example the AESGP one, which stresses the uniqueness of its kind of medicinal products where not only genetic information but the entire plant material is sourced continuously from nature and therefore requires a sustainable supply chain. This case is identical to the cases of certain leading pharmaceutical products produced in Brazil by Brazilian companies using Brazilian biodiversity, such as Acheflan produced by Ache and Regederm produced by Pelenova from rubber trees. In both these cases, besides the research and development part of the pipeline, the product development needs a constant supply of raw material that is cultivated by suppliers companies, that according to the new draft Brazilian ABS legislation (see Paragraph 1.3) are not in these cases doing any "access" to GR, so are not bound by the legal obligation to register. Possible solution for this issue will be considered in Chapter 4 (Paragraph 4.3.1).

The AESGP code of conduct is therefore the only one stressing that the user should undertake best efforts to create a clear and transparent structure, with explicit definition of responsibilities between all parties in the whole supply chain;

and in stressing the importance of the role of the ABS Clearing House created by the Nagoya Protocol in sharing and making available information related to ABS. Moreover, AESGP stresses that most of the ABS principles are already fulfilled by companies in their daily practices: for examples many obligation of article 4 of the Nagoya Protocol are covered by Annex 7 of the EU Guidelines on Good Manufacturing Practice (GMP) on the manufacture of herbal medicinal products and the Guidelines on Good Agricultural and Collection Practice (GACP) of the European Committee on Herbal Medicine Products , since a detail documentation along the supply chain is a key aspect of these two guidelines. The date and place of access to GR are always documented, as this is part of the marketing authorization process. The essential information required by article 4.2 (a) (2) of the Nagoya Protocol is found in the documentation required by the GMP and the GACP. The GMP also covers requirements of traceability such as information on subsequent users of GR or TK. This is an important aspect that deserves attention also in the framework of the Brazilian reality. These examples given by the AESGP refer to private standards of the sector: they have been referred to in the literature as useful tools to ensure a better ABS compliance within the industries (Oliva, 2012).

Private standards refer to all the standards that are adopted at the industrial level to comply with legal requirements. The most common examples are the eco-labelling system adopted by food industries' associations. They require and independently monitor information-gathering and measures to address any problems with regards to legal compliance. Significantly, private standards are based on traceability. Such minimum requirements, along with third-party verification, make private standards particularly relevant to establishing and monitoring due diligence (Brack, 2008).

Private standards commit their members or clients to ethical and sustainable practices, including ABS best practices. They are developed through multi-stakeholder consultations within a bottom-up approach. In meeting the challenge of monitoring and evaluating utilization of genetic resources for compliance with ABS requirements, private standards bring to bear relevant traceability systems, reporting requirements and independent audits. Such measures provide necessary incentives for companies to give concrete implementation to the principle of due diligence in their systems, as well as to go beyond legal compliance, building a business case for the ethical use of biodiversity. Private standards may have a role in monitoring and evaluating ABS implementation: they indeed require traceability through each step, actor and dynamic in the value chain. They generally include reporting requirements, as well as independent monitoring of compliance through third-party audits. The same information, considered essential to address adverse social or environmental impacts are equally important in the ABS context, providing ways to collect information on the origin of genetic resources, their terms of utilization, and any associated traditional knowledge. Private standards also improve awareness within the sectors, also in countries that have not signed,

ratified or implemented ABS provisions in the CBD and the Nagoya Protocol (Oliva, forthcoming).

Therefore, recognizing the investment and experiences that have gone into developing and putting these tools in practice is essential to ensure more effective regulations, as well as to encourage actors to engage in finding solutions and pioneering best practices (Oliva, forthcoming). Private standards are interesting also in the light of EU ABS Regulation which includes due diligence requirements that oblige users of genetic resources and associated traditional knowledge to gather and present information on access and compliance with applicable legal requirements (EU ABS Regulation, Article 4). To comply, the Regulation foresees that users could build on existing guidelines and practices developed for different sectors (EU ABS Regulation, Article 8), such as the associations of users that could present their procedures for recognition as best practices and take a role in monitoring how these practices and due diligence requirements are implemented (EU ABS Regulation, Article 9).

Standards have long existed as criteria for the manufacturing and supply of products and services with the aim of making, developing, manufacturing, and supplying products and services in a more efficient, safer and cleaner manner. These 'private' standards have proven no less legitimate because of their development or operation through entities outside of governmental structures. This is because their authority relies not on state sovereignty, but on factors such as transparency, multi-stakeholder governance, synergy with public policy, engagement of economic actors, and third-party verification of compliance (Oliva, forthcoming). Creating a dialogue with companies and other actors involved in the pipelines of the utilization of GR and associated TK is one tool used to promote more constructive policies on ABS, and to ensure better implementation. In Brazil, for example, private companies, industry associations and multi-stakeholder groups have been gathering together under a "Biodiversity Coalition" to actively exchange ideas with the government and other on concrete proposals to implement ABS requirements and arrangements. At the international level, technical discussions and exchanges of experiences are also supporting mutual understanding and building consensus on ABS (UEBT, 2013).

To date, the sector that showed more significant commitment to ethical practices, such as biodiversity conservation and ABS respect, is the cosmetic industry (Wynberg, 2013). It is also the one more involved in the use of private standards in general (Oliva, forthcoming). Currently, few private standards include requirements on ABS, but the number and potential is growing. For example, a recent study found that 20 out of 36 sampled environmental standards made reference to the Convention of Biological Diversity (UNEP, 2011). Their importance in implementing ABS has been recognised also by an informal expert meeting on the Nagoya Protocol.

3 THE PHARMACEUTICAL SECTOR IN BRAZIL

The Brazilian pharmaceutical sector has been chosen as the focus of the present study. This brief chapter is meant to introduce the sector with basic background information, and to describe the research and development pipeline to be considered for the monitoring and tracking system developed in Chapter 4.

The research undertaken in the scope of the present study revealed that no comprehensive analysis had in the past been undertaken to describe the pipelines of the Brazilian pharmaceutical sector, and its main exchange patterns of GR among the different users within the pipeline. Therefore, only fragmented information could be collected during the research, mostly through the interviews conducted by the consultant at the premises of three Brazilian pharmaceutical companies (Achè, EMS and Pelenova) and one culture collection (the Brazilian Collection of Environmental and Industrial Microorganisms – CBMAI). Given the impossibility to gather comprehensive and detailed information, and given that the conducted interviews (not required by the ToR) could not be consider as an adequate statistical sample, the study could not adequately cover all the important features of the sector. Chapter 4 therefore recommends to undertake comprehensive studies at the governmental level for all the main industrial sectors interested by the exchange of GR.

3.1 MARKET SIZE AND POTENTIAL MARKET

Brazil is among the five largest pharmaceutical markets in the world in terms of unit sales and the 8th in market size. Brazilian pharmaceutical market annual growth rate is of 15%. In 2011 Brazilian and Chinese markets grew more than 20% (CBD Secretariat policy briefing). The pharmaceutical industry in Brazil has increased its production by 50% within 5 years.

Market estimates (in US $millions)	2011	2012	2013 estimated
Total market size in Brazil	25,690	25,409	25,517
Total local production	20,643	20,063	19,787
Total exports	1,453	1,494	1,270
Total imports	6,500	6,840	7,000

Table 1: Brazilian pharmaceutical market

Source: http://export.gov/industry/health/index.asp?node3=health data from 2012

The national Brazilian pharmaceutical companies are only responsible for a minority of domestic sales: foreign firms mostly, from the United States and Europe, along with their Brazilian subsidiaries, supply 70% of the market.

Whereas large multinational companies that locally produce their brand-name products are important players, large national companies hold a significant share of the market (MOEZ, 2012).

3.2 EXPORTS AND IMPORTS

According to Brazil's Pharmaceutical Industry Syndicate (SINDUSFARMA), Brazilian pharmaceutical product imports in 2011 reached US$6.84 billion. This reflects a 4.6% increase over the previous year's level.

Generally speaking, exports have been growing at a faster pace than imports, but their overall value remains lower. Therefore, Brazil´s trade balance continues to post deficits for pharmaceutical products, and remains dependent on imports. The Ministry of Health perceives this dependence as a major vulnerability, and its reduction is one of the main objectives of public policies for the sector (OSEC, 2010).

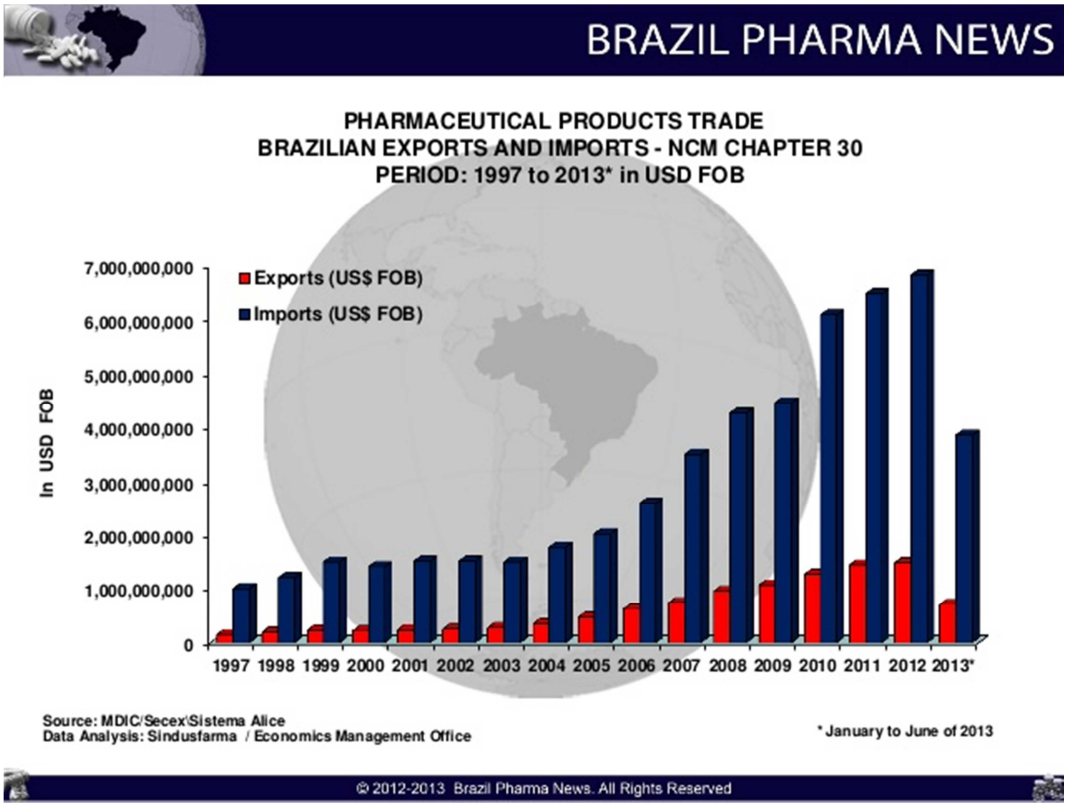

Figure 1: Brazilian pharmaceutical imports and exports
Source: Sindusfarma, Pharmaceutical Products Manufactories Union in the State of Sao Paolo http://www.slideshare.net/julianelewis/brazil-pharmaceutical-market-indicators-20032013

Imports of medicines into Brazil are predominantly carried out by the subsidiaries of international laboratories established in the country. They are also responsible for the biggest part of exports, but the share of domestic laboratories tends to increase (OSEC, 2010).

Raw materials (active ingredients) are also imported; the value is estimated at 2 billion R$ per year. Most of the pharmaceutical producers are also importers, as they normally import raw materials to produce the medicines.

The Brazilian government has developed a policy to promote the development of a national pharmaceutical industry. It aims at enhancing a national production base of pharmaceutical chemical products, as well as medical equipment. The targets are to reduce the annual foreign trade deficit on health-related goods.

3.3 RESEARCH AND INNOVATION

The R&D investment from Brazilian private laboratories has traditionally been very low, since patent protection was only extended to pharmaceutical products in 1997. Private laboratories spend a small (6%), but growing part of their revenue on R&D. A big part of this effort was directed at incremental research. Altogether, Brazil already has the capacity and expertise to do basic research and clinical tests, however it still lacks infrastructure for drug discovery and for pre-clinical tests due to the lack of infrastructure, particularly in the biotech area. Certain toxicology studies and special chemical tests are not available in Brazil yet (OSEC, 2010).

Most Brazilian pharmaceutical laboratories lack the know-how and scale to produce their own pharmaceutical ingredients. Apart from a few synthetic products (like paracetamol and vitamin C) and fermentation products (like antibiotics and enzymes), production is usually limited to the final synthesis, using fine chemistry ingredients from external sources. As a consequence, almost 80% of the demand in terms of value is covered by imports (down from 94% back in 2003).

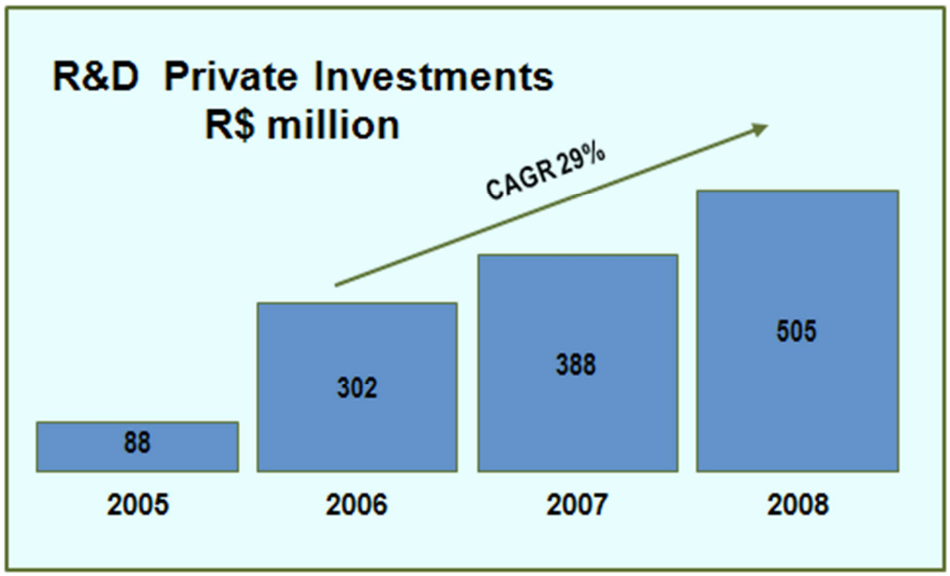

Figure 2: R&D Investments from Brazilian Private Laboratories
Source: Febrafarma report Brazilian Pharmaceutical Innovation

It appears that Brazilian companies are changing their business strategies. They are starting to perceive innovation and the development of new medicines as essential to sustain and increase their market share. Apart from collaboration with universities and other external research institutions, they are setting up and improving their own research centers.

R&D investment by foreign companies in Brazil represented 56% of the total amount of total R&D expenditures.

Research and innovation is still concentrated in the hands of public institutions. There are more than 100 small biotech companies, most of them located in clusters linked to public universities and research centers. The innovation activities are highly concentrated in public universities in Brazil, and 75% of the Brazilian researchers are linked to universities.

A large portion of Brazilian pharmaceutical companies produces either generics, or phytoterapic products, and therefore do not “innovate” in its most traditional understanding.

3.4 SOURCE OF RAW MATERIALS

Brazil relies on foreign raw materials and imports more than USD 2 billion worth of active pharmaceutical ingredients per year. Approximately 85% of the raw materials used in the production of generic drugs in Brazil are imported (http://export.gov/industry/health/index.asp?node3=health data from 2012). Brazil’s

amazing biodiversity has been little exploited so far, but might attract more investment in research centers if registration procedures were facilitated.

3.5 PIPELINE COMPLEXITY

In most sectors today demand for access to wild GR from biological diverse sources has declined, even as interest in GR overall has increased. (Laird and Wynberg, 2012).

Discovery of new molecules requires only a few micrograms, due to the advances in technologies. Therefore returning to the provider countries to obtain raw materials for expanded research, which has long been an important component of monitoring in bioprospecting agreements, may no longer be a critical step in R&D (CBD Secretariat policy briefing 2013).

The pharmaceutical sector is still the most R&D intensive sector, even though R&D funds are decreasing also due to the economic crisis. The pharmaceutical sector recently relied more and more to the diversity found in existing collections and one's own backyard, rather than search for new natural products (thanks also to the development of genomics) (Laird and Wynberg, 2012). Natural products as a source of molecular diversity for drug discovery and development have been overshadowed by approaches using combinatorial chemistry and biology, however genomics has once again made them interesting sources of chemical diversity (Laird and Wynberg, 2012).

As mentioned in Chapter 1 the legal uncertainty of the present ABS Brazilian legislation lead several pharmaceutical companies (Aché and EMS for example) to drop the part of in-house research and development using Brazilian biodiversity: either they do innovation using biodiversity of a different origin or concentrated on producing generics, or they focus of production of medicines for which no innovation is involved.

The supply chain is very diversified: some companies buy bulk unprocessed herbs, others may process plants into extracts, and a few might run screens, identify active compounds and undertake clinical trials, much as pharmaceutical or biotechnology industries.

The value chain illustrated below in the figure combines all the different values chain of the sector in Brazil: from the innovation chain usually starting with a public private collaboration between companies and universities and the less research intensive value chain of the national industry not doing innovation but focusing on phytoterapic products or food supplements.

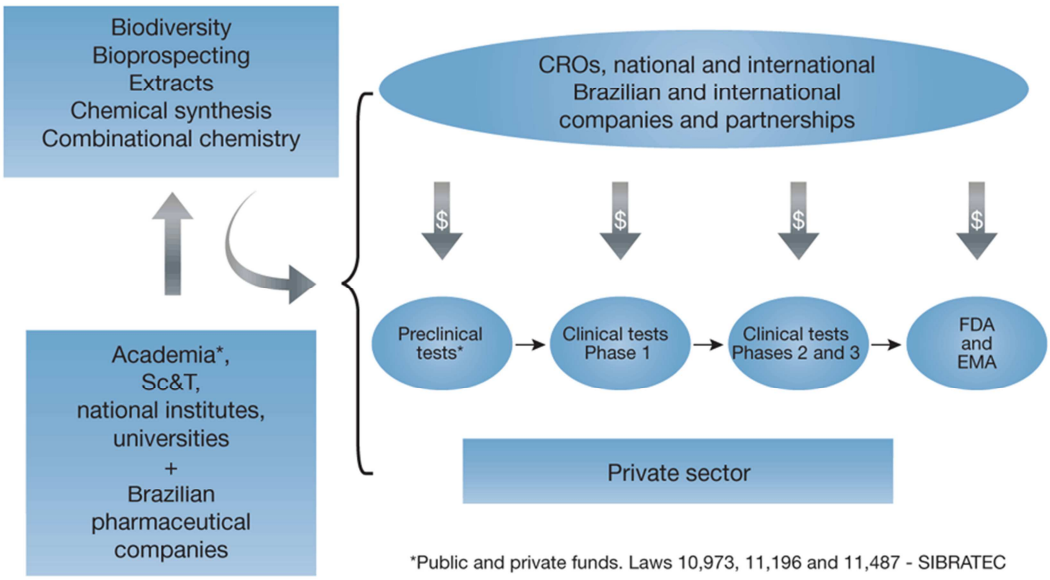

Figure 3: Brazilian pharmaceutical value chain http://www.sibratec.ind.br

This latter is in part common with the cosmetic sector: local dealers source plants from local growers or collectors, purchase them and sell them to companies doing the extract or they do themselves the extract and then they sell the extract to pharmaceutical companies. Considering the changes that the new Brazilian ABS draft legislation if bringing about, it is important to understand how the new legislative framework applies to these two different paths. They will be analysed when illustrating the proposed monitoring and tracking system in Chapter 4.

3.6 REGULATORY PROCESS

The regulatory process to get a pharmaceutical product into the market in Brazil is of competence of ANVISA, the National Health Surveillance Agency. In Brazil the registration of medical and pharmaceutical products with ANVISA (Ministry of Health) is mandatory. ANVISA is the regulatory agency that controls the management, imports, storage, distribution and sale of health related products and services in the country (see http://www.anvisa.gov.br). The Agency's competences embrace regulation, control and inspection, including the concession of drugs registration permits, which are compulsory for both local production and imports.

Since ANVISA was established in 1999, the registration of drugs and the acquisition of manufacturing permits became slower and more expensive. On the positive side, the Agency's high sanitary standards brought about a significant improvement in the manufacturing practices and thus promoted the quality of medicines sold in Brazil. ANVISA has adopted national guidelines for Good Manufacturing Practices and quality control, which refer to WHO

recommendations. There are also Good Laboratory Practice guidelines which follow the OECD standard.

Product registration can only be granted to companies established in Brazil and duly registered with ANVISA. This can be either the local manufacturer and/or the local company (Flanders Investments and Trade, 2011). The license remains valid for a period of 5 years.

Besides its competences upstream in the value chain dealing with drugs registration, ANVISA has competences also downstream in the pharmaceutical value chain. ANVISA is in fact also inspecting the suppliers of raw materials and the suppliers of extracts often involved in the pharmaceutical pipeline (see Paragraph 3.5), and it is also certifying them.

Chapter 4 is therefore looking into a possible integration of new tracking requirements into the industrial pipeline and the associated information requirements, within already existing commercial practices, such as the ones done by ANVISA. ANVISA has a capillary structure in each city; therefore its competences could be useful in the view of the adoption of a decentralized system.

4 A SYSTEM FOR MONITORING AND TRACKING

An effective tracking, monitoring and documentation system "could reduce the costs of accessing genetic resources; gradually decrease asymmetries of information between users and providers; facilitate the capture of non-monetary benefit-sharing; generate a more positive social environment towards bioprospecting and create incentives for users to comply with ABS legislation" (Fernandez Ugalde, 2007, p. 5). The best way to achieve ABS with effective socio-economic benefits is to build on existing procedures, to make the appropriate linkages between the various actors, and provide for the necessary incentives to the users so that ABS is effectively more beneficial to all and does not require coercive measures or penalties (WFCC - TRUST, 2014).

Tracking (tracing) systems involve procedures that follow the international movements of genetic resources, from original provision all the way up to inclusion in a commercial product or other inventions, including those applying for patent protection. "A tracking system may include provisions that require the tracking of each and every transfer, or it may guarantee that adequate data, sources and mandates are available in case these are needed in those individual cases in which tracking is regarded warranted" (Eaton et al., 2007, p. 21). Tracking refers therefore to following the flows and use of genetic resources. A system for tracking genetic resources would have to provide a means for providers to track the uses of the data and information derived from their genetic resources.

"The task of tracking successive uses of such information, although complex, is theoretically feasible and would require the crafting of appropriate metadata, careful utilization and implementation of a persistent identifier system and development of custom tracking applications. However, it should also be understood that such a system would have to accurately reflect our current and future knowledge of biology" (Garrity et al., 2009, p. 3).

On the other hand, "monitoring refers to a regular assessment of the functioning of the access and benefit-sharing system as a whole": monitoring should answer questions on the effectiveness of access and benefit-sharing agreements (Eaton et al. 2007, p. 21). Monitoring systems may function to inform all stakeholders involved about international exchange of genetic resources, in particular as it relates to the objectives of international agreements. For what concerns monitoring the Nagoya Protocol and the EU ABS Regulation choose to assign to checkpoints the role of monitoring steps where users have to demonstrated that they have acquired genetic resources in compliance with legal requirements. The burden of proof has been put on the users, creating as such an incentive for users to be ABS complaint.

Tracking and monitoring are important components of the process of verifying whether or not genetic resources are being utilized in the form which was originally agreed upon. Tracking and monitoring in themselves pose important challenges and imply a series of costs which will have to be borne by the user of genetic

resources, the supplier or a potential consumer of a product, depending on the specifics of the case (Eaton et al. 2007).

As demonstrated in Chapter 1, both the analysed international, regional legal and national frameworks already contain several obligations in terms of tracking and monitoring for the users of GR. Taking into consideration the self-regulatory efforts of concerned actors (Chapter 2), as well as the particulars of GR value chains of the pharmaceutical sector in Brazil (Chapter 3), the proposed system will suggest concrete steps to build an effective tracking an monitoring system, exploring several pathways towards such goal, and illustrating different options that could be pursued.

4.1 EFFECTIVENESS OF A SYSTEM OF TRACKING AND MONITORING

From an economic point of view, the major challenge seems to rest in the need to balance the costs and benefits of a monitoring and tracking system. Simply put, the transaction costs involved should not overweigh the system's potential benefits. The costs of documenting resources and implementing a regime to monitor resource flows need to be carefully evaluated, especially as the vast majority of resources being collected will never become the subject of research for commercialization purposes, let alone a single product with very high market value. During an international workshop on the Practicality, Feasibility and Cost of Certificates of Origin, it was pointed out that placing onerous requirements for certificates at the point of collection could then prove counterproductive, both for science and legal implementation, and could place onerous burdens on providers of biological resources who could find themselves with large administrative costs (Dedeurwaerdere et al., 2004). Participants noted that in order to determine the viability of any system, it will be important to consider, where possible, the use of existing infrastructure, human resources and checkpoints (Dedeurwaerdere et al., 2004), stressing the importance of involving stakeholders more greatly. The commitment of industry associations and research institutions is seen therefore as a key element. As it will be illustrated later, putting the responsibility of reporting to the users will help reducing the costs.

The best practices, the private standards and the tracking and monitoring requirements that are already in place within legal frameworks (Chapter 1) and the soft-law frameworks (Chapter 2) need to be reflected in any system that aims at being cost-efficient, effective and feasible. Therefore the following paragraphs illustrating the features of the proposed system will make adequate references to the already binding legal obligations and to the lessons learnt from the codes of conducts and the best practices illustrated above.

4.2 THE MONITORING AND TRACKING SYSTEM

The approach taken by the present study is that tracking is only one part of the broader framework that aims at ensuring ABS compliance, and it cannot work in isolation from the other features of the framework. This framework is made up of different tools that are fundamental for a tracking system to operate and therefore to ensure monitoring of GR use, including pre-requisite of awareness of stakeholders; contractual monitoring and tracking; the use of a unique identifier; and institutional monitoring through the checkpoints (of the provider and the user countries) up to the ABS Clearing House.

Paragraph 4.2 will illustrate these tools in order to offer several options that could be of guidance to build up a tracking and monitoring system. The different options, together with the suggestions by the consultant are illustrated in italics.

As shortly to be presented the proposed monitoring and tracking system focuses on two main features: the three interoperable and interconnected databases of the already established administrative procedures (the registry and the authorizations' and notifications' databases of the draft ABS Brazilian legislation - See Paragraphs 1.3 and 4.3.4) and the use of a scientifically based global unique identifier (See Paragraph 4.3.2) when possible.

4.3.1 RAISING AWARENESS AND IMPROVING KNOWLEDGE OF THE SECTORS AND THEIR BEST PRACTICES

- *First of all, according to the opinion of very high-level practitioners and as underlined by the main international codes of conduct (See Chapter 2), it is of paramount importance to raise awareness of the ABS principles within all the sectors that are dealing with genetic resources, from the scientific one to the industrials. The basics of ABS training should take place in every life sciences course, in ex situ collections and at sectoral associations' annual meetings. The legal framework and the procedures to be respected should be clearly illustrated, together with their implications for scientists and industrial personnel. Stakeholders should understand that it is in their interests to be ABS compliant.*

  The costs of these actions should be partly covered by public funds and partially by internal funds of the stakeholders involved in the system. As they have great interest in ensuring their own compliance, they should be willing to contribute to the financial efforts as well.

- *As suggested by the CETAF code of conduct, the various practitioners working with GR should be trained also on the fact that only certain legal representatives of the institution they work for are allowed to sign legal document concerning the use and transfer of GR. Such simple issues should not be taken for granted, in order to avoid legal uncertainties.*

- *In every publicly funded grant for scientific research on genetic resources, there should be a section requiring compliance with ABS rules, as it is for example required by article 7.1 of the EU ABS Regulation (See Paragraph 1.2). This feature is part of the awareness-raising action for stakeholders, but it is already a feature pertaining to checkpoints.*
- *Finally, as prerequisites to develop a monitoring and tracking system, it is important to:*

✓ *Improve the knowledge of the different sectors' pipelines through the help of studies developed at the Governmental level (publicly funded research agencies for example).*

✓ *Improve the knowledge of the exchange patterns of genetic resources between collections and other actors, also at the transboundary level*

✓ *Improve the knowledge of the exchange patterns of genetic resources within territorial boundaries, addressing crossings between basic research, applied research and product development*

Confidentiality that is granted to certain contracts might hamper these tasks; therefore some incentives could be given to private actors in exchange for their sharing of information with CGEN only for the purpose of the development of these studies. The studies could be kept confidential and not be disclosed to the public.

The very basis of an efficient tracking system is a good level of trust among partners which is built on the use of framework standard agreements, long lasting working relationships at the scientific and industrial level, exchange of personnel, the establishment and respect of codes of conducts and best practices among stakeholders. These are fundamental components considering that in cases of international movement of GR, once they leave the provider country, ABS compliance depends first of all on the effectiveness of user's compliance by the different stakeholders. Moreover as seen in Chapter 1, in countries Parties to the Nagoya Protocol user compliance is further strengthened by compliance measures taken by Parties in accordance with articles 15 and 16.

- *Long-lasting reliable relationships and dialogue between the Government (CGEN and the Ministerio do Meio Ambiente) and the sectors should be strengthened. A great example to follow is the "Biodiversity Coalition" platform (See Paragraph 2.2) where private companies, industry associations and multi-stakeholder groups have been gathering together to actively exchange ideas with the Brazilian government and others on concrete proposals to implement ABS requirements and arrangements.*
- *The Government should encourage the development of codes of conduct and sectoral best practices, and recognize the ones that are already in place. Such encouragement could lead to a system of recognition and reward for the more advanced and reliable sectors, as it is for example envisaged by article 8 of the EU ABS Regulation, which grants the*

possibility to recognise best practices and to allocate rewards to the associations of users or other interested parties that develop such best practices (See Paragraph 1.2). If such rewards are put in place, such as for example lighter administrative procedures, the sectors could see it as incentive to be compliant with the codes and best practices.

- *A special recommendation addressed to the Brazilian Government would require an awareness-raising action among sectors of users on the already existing codes of conducts and best practices. From the interviews at the premises of pharmaceutical companies and culture collection the consultant unveiled a barely inexistent awareness of the main codes of conducts and best practices illustrated in chapter 2. The users are not/barely aware of the main international networks relevant for the pharmaceutical sector (BIO, GGBN, IFPMA, IPEN, WFCC) and their related activities, therefore they are missing out the possibility to benefit from their experiences and capacity building projects, such as for example the Global Catalogue of Microorganisms (GCM) illustrated in Paragraph 2.1.3.*
- *Examples of best practices or elements of codes of conducts that could be integrated into the proposed monitoring and tracking system will be mentioned in the relevant sections*.

From the point of view of the industry best practices looking at the pharmaceutical pipeline and the main business model (Chapter 3) one issue related to the Brazilian registration procedure needs to be considered carefully. In the part of the pharmaceutical pipeline where there is no innovative research and development step and the compound that is used to produce the product is a known extract from raw materials (a plant for example), the registration process is done by the company buying the extract from the suppliers, because this is the first entity exercising access in the terms of the definition of the new ABS Brazilian draft legislation. This path could be critical: some of the above mentioned information of the minimum ABS dataset might be lost from the passage between the first supplier of raw materials to the second supplier of the extract to the first user that start doing research and development.

The proposed tracking and monitoring system highlights the following two possibilities to solve this issues:

1. *First the fact that the first two entities that are often involved in the beginning of the research and development pipeline of the pharmaceutical sector (supplier of raw materials and suppliers of extract) are not bound by the obligation to register their access to GR (because it does not involve research and development step therefore it does not account as "access" according to the definition of the new draft ABS legislation) might be solved through a natural process of selection of reliable partners by the companies doing research and development. These companies, bound by the obligation to do the registration have all the interest to choose the most*

reliable suppliers that are providing the most reliable information on the origin of the resources and/or the traditional knowledge associated to it. These companies will naturally not use suppliers that are not reliable enough. As a matter of fact, in case of incomplete registration by the company unable for example to say where the GR has been collected and when, the company will not be able to sell the developed products in the market (within the new Brazilian ABS draft legislation). Therefore this constitutes a huge incentive for the companies to use only suppliers that are reliable. But this option is only based on a natural selection process that does not give any legal certainty to the system.

2. *Secondly the competences of ANVISA linked with the beginning of the pharmaceutical pipeline could be used to close this potential loophole in the system:*
    - *Since ANVISA is also inspecting the suppliers of raw materials and the suppliers of extracts and it is also certifying them, an ABS step could be inserted within this certification process as a compulsory declaration for the suppliers on where the resources and the eventual associated traditional knowledge are from. ANVISA has a capillary structure in each city; therefore opting for such a tracking system would mean adopting a decentralized system.*
    - *It is therefore highly recommended to look into a possible integration of new tracking requirements into the industrial pipeline and the associated information requirements, within already existing commercial practices, such as the ones done by ANVISA illustrated above.*

Relying on the industrial administrative chain of the pharmaceutical pipeline is useful because ANVISA has the double advantage that ANVISA is involved in the administrative procedure both upstream in the value chain and downstream. As we saw in Chapter 3 ANVISA is inspecting suppliers companies downstream in the value chain. Moreover, ANVISA is also involved upstream in the value chain: it is in fact responsible for drug registration and licenses to pharmaceutical laboratories and to other companies inside the pharmaceutical production flow. The agency is also responsible for establishing regulations applicable to clinical trials and drug pricing, which is carried out by the Chamber of Drug Market Regulation (CMED). Together with states and municipalities, the agency inspects factories, monitors the quality of drugs, exercises post-marketing surveillance, takes pharmaco vigilance actions, and regulates drug promotion and marketing. Moreover, ANVISA is in charge of analysing patent requests related to pharmaceutical processes and products, in partnership with the National Industrial Property Institute (INPI).

It is therefore recommended to integrate the record of ABS relevant information within the already existing industrial legal requirements or best practices eventually developed by the sector if any.

4.3.2 SCIENTIFICALLY BASED TRACKING: GLOBALLY UNIQUE IDENTIFIER

The importance of the precise identification of a GR is well explained by the following sentence: “Before any species of plant, animal or microbe can be protected or become part of a sustainable development effort, it must first be identified and given at least a trivial name so as to distinguish it from all others” (Garrity et al., 2009, p. 29). Therefore according to the proposed monitoring and tracking system, the most effective tool of the proposed tracking system is a scientifically based globally unique identifier (GUI) that should be able to identify the GR and link it to the physical position where it is stored, to the legal documentations prescribing its terms of use (PIC, MAT, MTA) and to the most precise possible scientific description. This paragraph introduces how the consultant sees the scientifically based global unique identifier working.

It needs to be considered that the sampling of biodiversity can give rise to different situations that complicate the tracking and the use of unique identifiers. Only rarely in fact the resource is utilized as a GR in itself (case A). Much more frequently, several and different samples/strains/enzymes etc… are isolated (case B) from a single GR for research purposes. They can all lead to different research paths because the different components are studied for the different properties they possess. Furthermore, several different GR may be isolated from a single sample (case C) (for example from a sample of marine water several samples of different microbes can be isolated), while several samples/strains/enzymes could also be isolated from these different GR and combined within a single product (case C.B).

- Case A. One single GUI is associated to one single GR (very rare)
- Case B/C and C.B. Several GUIs are associated to one GR/sample

“What is required is a mechanism to track the fate of multiple genetic resources as each is transferred from one party to another and various abstract and concrete products are generated along the way” (Garrity et al., 2009, p. 5). There is growing use by a wide range of actors of systems of unique identifiers, including barcodes, and digital object identifiers (DOIs) as a means to identify resources and aid in their tracking . Use of identifiers enhance the possibilities for maintaining a link between resources and the certificate and terms and conditions applying to them. Giving the possibility to have a scientifically based GUI, once it is possible, gives to the system a further option of linking the GUI to the exact specimen, which is very valuable in terms of tracking and monitoring.

Within the framework of the new draft ABS Brazilian legislation (See Paragraph 1.3), at the moment of registration and authorization, the PIC is published by CGEN in the ABS Clearing House, thus issuing an IRCC containing the unique identifier. Even though the IRCC contains the description of the “subject matter or genetic resources covered by the certificate” as required by article 17.4 (f) of the Nagoya Protocol (See Paragraph 1.2), it is unlikely that at this stage the GR are scientifically identified, therefore this identifier usually does not include complex scientific information on the resources.

The proposed monitoring and tracking system is based on a scientifically based unique identifier: in order to link the unique identifier with the scientific information, it is necessary to issue a scientifically based unique identifier which would therefore be truly globally unique and which would be based on the complete scientifically based data. This cannot be done at the Governmental level because it implies high scientific knowledge and equipment.

Therefore within this scenario there could be two options:

A. *The scientific analysis is done at the moment of access, therefore at the moment of the registration but at the level of a public ex situ collection that should be part of a network of accredited collection within the country, being it a microbial culture collection, a botanical garden or any other types of public collection. As such the scientific globally unique identifiers associated with the several GR/samples could be already included into the PIC or permit published in the ABS Clearing House, therefore in the IRCC.*

   This would be the most reliable option counting on the independence and accuracy of the collection that undertakes the scientific analysis, but there might be an issue of capacity of the collections and of funding. Either the costs of this complete scientific analysis are borne by the user, the entity registering access in the Brazilian registry, and a system of incentive could be provided by the Government to attract the users towards the covering of the costs; or this option would work only within a system of well established network of ex situ collections that have enough capacity and funds to undertake the role.

B. *The scientific analysis is done by the user, being it a public or private entity, as part of the research and development process, not necessarily at the moment of the registration. In this case, when the CGEN issues the PIC and registers it at the ABS Clearing House, it will also associate to this IRCC a wide series of unique identifiers all associated with the GR. These series of unique identifiers will then a posteriori be associated with the actual scientifically based ones produced by the user, after the scientific analysis. CGEN would then take advantage of the possibility to amend the information contained in the IRCC as envisaged by the COP/MOP meeting held in October 2014 (UNEP/CBD/NP/COP-MOP/1/L.8 – see Paragraph 1.2). This option brings better cost-effectiveness, and is therefore more feasible. It is very similar to the option that is likely to be adopted by the Global Catalogue of Microorganisms in order to link the GCM to the ABS CH (UNEP/CBD/NP/COP-MOP/1/INF/8). However it is important to point out that the expertise of conserving ex situ microbial GR and the network of culture collections are much more advanced in the practices of cataloguing, tracking and monitoring the movement compared to other domain of GR. Therefore it is highly recommended to the Brazilian Government:*

   - *To foster the culture collections in Brazil within the Federación Latinoamericana de Colecciones de Cultivos (FELACC)*

- *To create incentives for all ex situ collections to publish their databases and make them available online*
- *To raise awareness of Brazilian culture collections of the capacity building opportunities offered by the Global Catalogue of Microorganisms project of the World Database of Microorganisms within the WFCC (Paragrapgh 2.1.3)*
- *To encourage the development of similar cataloguing experiences within other types of ex situ collections, either within the networks of such ex situ collections (see Chapter 2) or at the CBD level.*

Moreover, according to the current scientific knowledge and current state of collections, this option might be envisaged only for certain types of GR where scientific characterisation and institutional capacity are more developed (microorganisms, seeds for example). It is therefore suggested to enquire at the international level (CBD and international networks of ex situ collections) whether latest advancements in life sciences could make this option a reality for a broader set of GR, like animals for instance.

4.3.3 CONTRACTUAL TOOLS FOR MONITORING AND TRACKING

Legal certainty is the essential condition for users' compliance. Therefore it is of paramount importance for a provider country to adopt standard mutually agreed terms on terms of use and transfer to third parties and on monitoring and reporting duties on the users, being them national or foreign users, as suggested by article 17.1(b) of the Nagoya Protocol (See Paragraph 1.1), encouraging providers and users to include in all mutually agreed terms (MAT) provisions to share information on the implementation of such terms, including through reporting requirements. In fact, the main legal option to monitor and track the accessed GR and their use is the contractual one, through the reporting duties imposed on the users, the regulation of transfer to third parties and the regulation of material transfer agreement.

Whenever a GR is accessed in situ, mutually agreed terms need to be signed if an effective tracking and monitoring system is to be envisaged. This legally binding contract between the provider of the resources and the user should state with sufficient clarity the terms of use of the resources by the user, the terms of eventual transfer to third parties of the resources, and impose on the user the respect of several obligations, among which reporting to the provider on the use, transfer, research results and eventual steps towards commercialization, if this is allowed by the terms of use (concrete examples of reporting duties are illustrated below - see paragraph "Reporting duties"). This contract is the legal basis for the provider to claim that the user must respect certain conditions; especially in the cases these conditions are not contemplated by any national legislation or regulatory requirements.

Before discussing in details the content of mutually agreed terms to be signed, it is important to point out the following considerations in regards to the notion of change of intent within the Brazilian ABS new draft legislation. The change of intent is the change of the user's purpose of utilization from basic research to commercial research. This concept is anyhow still very much debated in the literature, since it is based on the distinction between commercial and non-commercial research, upon which no international agreement has been found reached. There are three ways to define the terms commercial/non-commercial as they are applied to the studying and further elaboration of genetic resources (GR) (Winter et al., 2012):

- One is related to the financial and institutional framework of the users utilizing the GR; it may be called the institutional definition.
- A second is related to the valorisation chain and its main purpose of developing a marketable product; it may be called the substantial definition.
- A third is related to the public or private realm into which the results from the research and development are placed; this may be called the functional definition.

By adopting the end of the pipeline as the trigger point for benefit-sharing, that is to say the moment that the end product reaches the market, and by adopting a system based on an ex ante agreement on the moment and the amount of the payment of the benefit-sharing, the new draft ABS legislation has solved in this way the issue of the change of intent between basic research and research and development. The new draft legislation has opted for a change of intent concept linked only with the final stage of the pipeline of the final product on the market, which therefore triggers a different administrative procedure: the notification. If a change of intent is occurring within the pipeline, the user is not subject to any different procedure than the registration: the registry would probably require the user to declare the change of intent but this does not trigger any duties on the user, within the draft new ABS legislation. This is one of the revolutionary features of the draft new legislation.

Therefore it would be counterproductive for the proposed monitoring and tracking system to complicate the system by focusing on such change of intent, based on different criteria to distinguish between commercial and non-commercial research.

Mutually agreed terms, within the Brazilian draft ABS legislation are signed in different moments, according to the fact that the trigger moment for the ABS procedure changes according to the type of users, the present system foresees two cases to be considered:

Case A – Research and development run by nationals and foreigners associated with nationals: access within the meaning of the legislation, is research and development, therefore these MAT are to be signed at the point of registration, which might not be the moment of access in situ.

Case B – Research and development run by foreigners not associated with any Brazilian entity: the trigger point for the beginning of the ABS procedure is access in situ or access ex situ by a foreign user, therefore MAT are to be signed at the moment of authorization given by CGEN either at the moment of access in situ or access ex situ.

REPORTING DUTIES

The reporting obligations are important tools for the provider country because these obligations are putting part of the costs and responsibilities of monitoring on the users. The limits of the reporting duties are nonetheless twofold. First of all, their enforcement is difficult; and second, the issue of the provider country's capacity to store, analyse and use this information is absolutely central to their efficiency.

Certain clear obligations in terms of reporting should bind the users doing research and development. These obligations should include reporting back to CGEN (and any other designated checkpoints) about:

➢ *The results of the use of the accessed GR and associated TK, and the eventual product developed (if this is allowed by the MAT)*

➢ *Every scientific publications produced upon the use of the accessed GR and associated TK*

➢ *Every transfer to third parties (in case this is allowed, see following paragraph)*

- *On the first point (the results of the research and development) there might be a clash with the confidentiality that might surround certain contracts. In case the user asks for confidentiality, it might not be possible to negotiate a reporting obligation on the results of the research, but still the user will be bound by the obligation to notify to CGEN once a product has been developed upon that research and it is ready to be put in the market. Therefore the final step of the end of the pipeline will be anyway recorded in the system by the notifications' database.*
- *The reporting obligations are fundamental steps for the flow of the information on the use and transfer of materials to be recorded and be available to the national competent authorities. However, the analysis of the reported information raises the issue of capacity of the receiving organization, whether CGEN or any other Brazilian institution. For a reporting system to be efficient, it is highly recommended for the entity receiving the reports back, CGEN or any other, to strengthen its capacity to analyse all the information and adequately react to them, in case they reveal possible situations of non compliance with ABS arrangements. This issue should be considered by the legislation in terms of financial capacity to be allocated for human resources and for technological needs to interpret the information.*

- *At this step the users, both national and foreign, should be required to deposit a duplicate/voucher of each the resources they start using, into a national ex situ collection. This is an important step for keeping trace of the original genetic resources that has been accessed by the user. This requires however that the Provider country has the capacity to store the materials and to maintain it. It therefore requires allocation of funds.*

As underlined above, considering that within the Brazilian draft ABS legislation the trigger moment for the ABS procedure changes according to the type of users, the present system foresees two cases to be considered for the modalities to sign MAT:

Case A – Research and development run by nationals and foreigners associated with nationals

Within the new Brazilian ABS procedure of registration, three options could bind users by certain specific reporting obligations:

Option 1. At the point of the registration the users signs (by clicking if the registration is an online procedure as envisaged) mutually agreed terms on the above-mentioned reporting obligations.

Option 2. Once adopted, the new draft ABS legislation will be complemented by implementing acts. This implementing legislation could impose on users some clear obligations in terms of reporting back to the competent national authorities.

Option 3. The implementing registration could prescribe the obligations of option 2 and the online registration could require the user to sign the MAT by clicking. This cumulative option is probably the most efficient.

Case B – Research and development run by foreigners

These cases imply the need for authorization by CGEN for the foreign users, whether these are commercially oriented or not. The authorization procedure requires the negotiation of MAT and requires a PIC. The fact that the authorization procedure is a more complex procedure (rather than an online registration), there is an incentive for any foreign users to associate with a national entity if they wish to access Brazilian GR and start research and development using genetic resources.

The MAT that bind the foreign users should also include clear and strict obligations for the users to report back to CGEN as illustrated above.

The existence and the terms of such contracts are especially fundamental when the user is from a country that is not party to the Nagoya Protocol: if such a contract is not signed and if the Brazilian ABS legislation and its implementing acts do not foresee anything to this regard, there would be no legal basis for the reporting duties to be imposed on the users, as a provider granting access to a user located in a non-Party can only rely on contractual measures against the user.

On the other hand if the user is from a Party to the NP, that Party has to comply with international monitoring obligations (article 17) by establishing checkpoints that collect or receive relevant information related to PIC and to MAT and/or the utilization of GR, and by imposing to the users to provide the relevant information to the checkpoints. This information will be then communicated to the relevant national authorities, to the Party providing PIC and to the ABS CH, therefore creating a flow of information that allows the Provider country to be informed about the users' utilizations.

If the user is from a EU Member State, it will have to report certain information to the competent authorities which will then transfer them to the ABS CH. As such the flow of information is granted also in case of transboundary access (See Paragraph 4.3.4).

It is interesting to note that the threshold for compliance control might differ from one national order to the other. For instance, if it is active within a EU Member State, the users will have to exercise due diligence.

THIRD PARTIES TRANSFER

Allowing third transfer of GR makes tracking more difficult and costly. The following options could be adopted in regards to third parties transfer of GR:

Option A. The easiest way to limit the reach of a tracking scheme is to prohibit through the use of contractual means the transfer to third parties of materials. As such any third parties interested in accessing that resource will have to ask another PIC and negotiate terms of use. This is the usual practice adopted by collections, recommended for example by the TRUST code of conduct for culture collections. This however has the negative consequence of hampering research and therefore reducing the possibilities of entering into a commercialization phase and therefore of getting back the share of the benefits. Such option would probably be opted for in cases of material transfer agreement (MTA) of GR abroad to foreign entities, when this occurs outside the framework of any international collaborative project, or if the transfer is asked for commercial purposes (change of intent – See above).

Option B. The adoption of a system similar to the legitimate exchange practice applied by culture collections within the TRUST system, could be implemented in the Brazilian pharmaceutical value chain most common business model where the research and development starts from a research path led by a publicly funded research institution (often a public university) and develops as a spin-off company from the university: the university does the registration and then the spin-off company is usually established involving at least part of the same scientific team. In this case the concept of legitimate exchange could be adopted for transfer to third parties working on the spin off project, sometimes in the same laboratory.

Option C. The adoption of a viral license that ensure that the conditions imposed by the provider country on the use of the material are imposed on the following users. The viral licence concept means that the original MAT (of the original ABS

agreement) would in this case travel with the material upon signature by the third parties accessing the resources of a contract imposing the same conditions, otherwise no transfer is allowed. The user is allowed to transfer the material to third parties if the third parties sign a new contract in which they commit themselves to respect the conditions of the initial ABS agreement. Every transfer to new third parties will require the signature of a MTA that makes the initial ABS agreement binding. The initial ABS should be attached to the MTA as an annex. This option has been adopted by the EU FP7 project Micro B3 (Biodiversity, Bioinformatics, Biotechnology http://www.microb3.eu) in the ABS model agreement that has been developed by the project to regulate access to marine microorganisms and benefit-sharing, and which has been utilized by the sampling worldwide campaign Ocean Sampling Day.

This option reduces the negotiation costs and guarantees the application of the legal conditions imposed by the Provider country.

Such option would be opted for in case of complete trust over the compliant implementation of the MAT by the subsequent users, as a control of compliance of the chain of the third parties would be rather burdensome by the provider.

Within the new Brazilian ABS procedure of registration, this option of viral license could be opted for when the user registering is:

- ✓ *An ex situ collection member of an international "network of compliance", such as the IPEN or the TRUST for example. AND/OR*
- ✓ *A user working within a publicly funded scientific project: transfer could be allowed within the team of the project, even if international. AND/OR*
- ✓ *For all transfer of GR between Brazilian users, as we have noted that the change of intent is not relevant for triggering benefit-sharing or any other administrative burden. Such case would foster the utilization of GR and research and development, without compromising the whole tracking and monitoring system already established by the registry and the notifications' databases.*

Benefiting from the best practices and the internal rules of either a well-established network of ex situ collections or a publicly funded research project would seem reasonable. Moreover this possibility of transfer to third parties could be offered to a category of users that have developed best practices as a reward (See Paragraph 4.3.1).

Within the Brazilian procedure of authorization in cases of foreign users accessing a GR or in cases of shipment of GR abroad the application of the viral license should probably be limited to cases of non-commercial utilization. To this end an approach to distinguish between commercial and non-commercial utilization would need to be adopted by the Brazilian implementing legislation. The reason to adopt a more burdensome option lies in the fact that control and enforcement of the viral license conditions abroad is even more difficult for the Brazilian authorities.

MATERIAL TRANSFER AGREEMENT

Another crucial contractual tool for an efficient tracking system is the use of Material Transfer Agreement (MTA) for the transfer of material from one user to another. This is fundamental for the tracking of movement from a research institution/culture collection to a private commercial user, through the value chain, to transboundary movement of GR abroad.

Considering the aim of the Brazilian new ABS draft legislation to establish a lighter ABS procedure to regulate ABS and the goal of establishing on the same time an efficient tracking and monitoring system that should therefore not run counter the first aim, a viable option to reach such a compromise is to recommended that the Brazilian registration procedure of the users is linked to the MTAs signed by the users. This option builds on what is already in place and it is therefore cost effective. As such a single registration can give rise to a single flow of information, where information related to the first access to a GR is linked to the subsequent access and use of the same by subsequent users, thanks to the record of all the MTAs within the registry. This is shown in Figure 4 at page 60.

In the event when users are faced with a request to ship materials abroad to non-Brazilian users, the Brazilian draft ABS legislation prescribes to go through the authorization procedure. The implementing legislation to the new draft should therefore take care of producing a special standard MTA to be used. This MTA should include obligations on the user to report to CGEN as seen above (See above). As for the conditions of transfer to third parties included in such special MTA please see the options illustrated in the previous paragraph.

4.3.4 The single flow of information of the three interoperable and interlinked databases

The proposed tracking system sees the three interoperable and interlinked databases (the registry, together with the authorizations' and the notifications' databases) as the ideal flow of ABS information. After the first registration by the first user doing access, every subsequent user would be required to continue recording the necessary information within the same flow of information. This flow of information would need to be linked with the information recorded by the authorizations' and notifications' databases (See Figure 6) and with all the relevant MTAs.

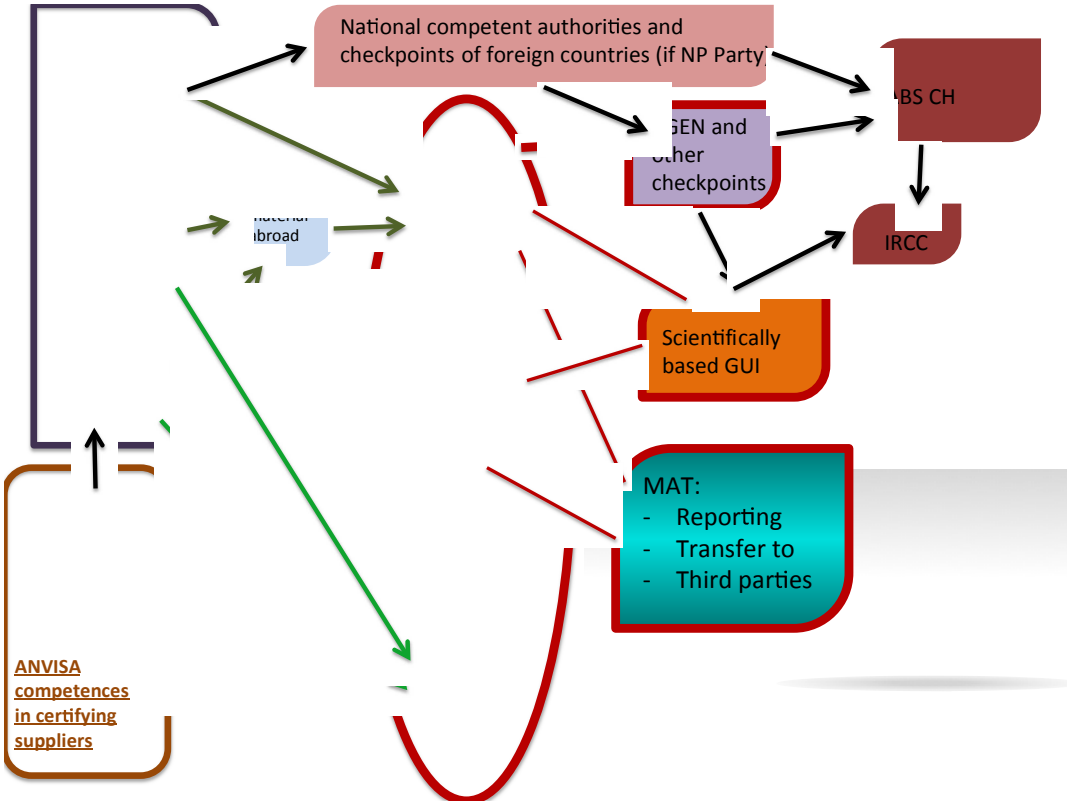

Figure 4: Flow of information within the proposed monitoring and tracking system based on the central role of a scientifically base GUI and the interoperable and interconnected databases of the registry, the authorizations' and the notifications' databases.

As already noted, the commonly understood change of intent between basic research and research and development according to the new ABS draft legislation does not trigger any benefit-sharing, nor any specific administrative procedure to be compiled with by the user, because the only triggering moment is the final stage of the product in the market. The change of intent between non-commercial research and commercial research is not relevant. What matters is the end of the pipeline and the moment the product is ready to be on the market and the fact that anyway all the information at all the different passages of the different users have to be recorded either in the registry or in the authorizations' and the notifications' databases. As long as the information are stored and accessible to the competent authorities that have to communicate to the ABS CH issuing the IRCCs, there is no need to complicate the flow of information with additional requirements in case of change of intent.

The implementing legislation might only considering integrating the information to be recorded at the registry with a different level of burden in cases when the commercial intentions (either because a private company enters the research and development pipeline; or because private companies funds are entering the research and development pipelines; or because the results of the research and

development are being protected through intellectual property rights – according to which definition of change of intent the implementing legislation will adopt) are shown.

The registry should be filled in with the minimum ABS dataset, that is to say:

- *The description of the GR or in case of access from an ex situ collection, the collection identification (unique identifier)*
- *The date of collection in situ*
- *The date of accession in an ex situ collection if the GR has been accessed into an ex situ collection*
- *The geographical position of the in situ collection*
- *The contact details of the collector/the contact of the ex situ collection*
- *The PIC or the IRCC when available*
- *The description of the research and development project with the contact details of the responsible person that is legally entitled to sign legal documents.*
- *The strings attached to the use of the GR by the MAT (e.g. Conditions of use; transfer to third parties or not)*

A registry number could be associated to a GR or to a research and development pipeline and the subsequent user would only need this number to enter the related flow of information: they will not access all the previously stored information in case they are claimed to be confidential, and they themselves can be granted confidentiality in the information they give. Some items could be filled in but not being visible so the system record them but do not disclose them (as it is in the ABS CH). This system of course needs to be digitalized.

Once the registration is done, if the user is transferring the GR to another user (if this is allowed by the MAT) two options could be envisaged:

Option 1: The new user is required to fill in additional information within the same registry so the whole of the flow of information would be in electronic format online. The MTA signed by the subsequent user could be envisaged as on line clicking accepting the conditions that have to be imposed and declaring the necessary information such as the:

- *The description of the research and development project with the contact details of the responsible person that is legally entitled to sign legal documents.*
- *The description of any new GR that is included in the research and development pipeline when coming from the same provider country that is to say Brazil (if any is introduced) and this would amount to a new registration (with new information to be recorded as illustrated above).*

However this would allow the user to link this new registration of a GR (probably coming from another in situ or ex situ origin) with the previous one. This would ensure the record and the linkage of important information that might be useful at the end of the pipeline to determine which GR is a major element of adding value to the product, thus the trigger point for the share of the benefit according to the new ABS draft legislation (see paragraph 1.3.2).

Option 2: The new user signs a paper MTA with the previous user containing the legal conditions. However a copy of this MTA should be linked with the registry and be integrated in the electronic flow.

Having the three interoperable and interconnect databases (registry and the authorizations' and the notifications' databases) as the single flow of information has the benefit that since the national competent authorities (CA) have access to them, there is no need for the users to further communicate to the CA: an automatic online communication could be sent to CGEN and the other competent national authorities and checkpoints once every new steps of registration and notification are recorded. Authorizations' procedure on the other hand implies an active role for the competent national authority CGEN.

The registry should be accessible to checkpoints, or better they could be managed by checkpoints. This would allow to avoid duplication of flow of information from the users to the registry and then from the users to the checkpoints. It is always better to build on what is already in place and since the registration is the core procedure for gathering ABS information, this should be linked or integrated within a checkpoint. CGEN is one checkpoint and it is likely to be in charge of the registry as well.

This idea is also inspired by the suggestion envisaged by the CETAF and GGBN set of documents (Paragraph 2.1.2) according to which institutions may find it helpful to manage all required infranational, national and international legal documentation under the same policy umbrella; by doing this they will be able to use common database solutions and be more efficient.

The three interoperable and interlinked databases storing the related information are also linked with the ABS Clearing House through the use of the IRCC and the proposed scientifically based global unique identifier, and thanks to the role of CGEN as intermediary. They should be designed to be interoperable with the ABS CH database in order to increase efficiency. As suggested by the COP/MOP in October 2014 (Paragraph 1.2) in describing the modalities of operation of the ABS Clearing House the design of the ABS Clearing-house should be "interoperable and facilitate the exchange of information with other databases and systems, in particular Parties' databases, as well as databases of other instruments and organisations" (UNEP/CBD/NP/COP-MOP/1/L.8, p. 3).

The flow of information in cases of transboundary movements of GR through the pipeline can be easily granted in countries Party to the Nagoya Protocol and/or EU

countries thanks to the obligation of Article 17.1(a) establishing checkpoints that collect or receive relevant information related to PIC and to MAT and/or the utilization of GR, and by imposing to the users to provide the relevant information to the checkpoints. This information are then communicated to the relevant national authorities, to the Party providing PIC and to the ABS CH, therefore creating a flow of information that allows the Provider country to be informed about the users' utilizations. Moreover, as illustrated in Paragraph 1.2 if the user is from a EU Member State, it will have to report certain information to the competent authorities which will then transfer them to the ABS CH and to the national competent authorities.

As already noted, in countries that are not Party to the Nagoya Protocol, such flow of information needs to be ensured through the adoption of clear reporting obligations established in mutually agreed terms (Paragraph 4.3.3).

CONCLUSIONS

The present chapter suggests concrete steps to build an effective tracking and monitoring system, exploring several pathways towards such goal, and illustrating different options that could be pursued. The different options are all rooted in the applicable legal framework illustrated in Chapter 1 and inspired from the best practices illustrated in Chapter 2.

The study shows that many already binding obligations are functional for a tracking and monitoring system. Therefore the implementation of the existing obligations included both in the Nagoya Protocol and in the EU ABS Regulation will prove to be critical.

The proposed system of monitoring and tracking has tried to build up on existing structures in order to be cost effective, and in order to be in line with the simplifying efforts of the Brazilian draft ABS legislation.

The main two features on which the system is based are:

- The use of a scientifically based global unique identifier when possible, which allow the link with the physical position of the genetic resources, with the legal documents regulating its use and with the actual scientific information related to the GR, when possible.

and

- The three interoperable and interconnected databases of the registry, and of the authorizations' and notifications' databases of the draft ABS Brazilian legislation, that are to be linked with the MTAs signed by the users, the Clearing House databases and the Internationally Recognised Certificates of Compliance (IRCC) and the global unique identifiers.

The interoperable and interconnected databases ensure a single flow of ABS information that are to be recorded by the users and accessible by the competent

authorities and the checkpoints. Such a single flow, with operative options to safeguard confidentiality, allows to avoid duplication of the information to be reported by the users to the different authorities. Moreover since the databases keep track of the MTAs that are signed when GR are transferred, also abroad, and are linked to the ABS CH database, the flow of information covers also transboundary movements of GR throughout the pipeline.

Before setting up the different steps to establish the system it is of paramount importance to improve awareness of the stakeholders and the sectors on ABS; the knowledge of the different sectors pipelines and exchange patterns; to strengthen the role of sectors' best practices, codes of conducts and private standards and to raise awareness on the capacity building options that are offered by these networks to the stakeholders. Secondly it is important to adequately use the contractual monitoring and tracking opportunities offered by the mutually agreed terms and the material transfer agreements in imposing reporting requirements to the users and in regulating transfer to third parties. To this end the implementing legislation to the Brazilian ABS draft new legislation will be crucial for setting up certain standards and legislative requirements in line with the proposed tracking and monitoring system.

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