SCOPING PAPER No. 4, November 2019

# Protection of Medicinal Plant Genetic Resources in India

FITM acknowledges with thanks the support and guidance of the Ministry of AYUSH for undertaking this study.



*Published : November 2019*

**RIS**
**Research and Information System for Developing Countries**
**विकासशील देशों की अनुसंधान एवं सूचना प्रणाली**

Core IV-B, Fourth Floor, India Habitat Centre,
Lodhi Road, New Delhi-110 003, India
Ph.: +91-11-24682177-80, Fax: +91-11-24682173-74
E-mail: dgoffice@ris.org.in
Website: www.ris.org.in

# Contents

# List of Abbreviations

| | | |
|---|---|---|
| ABS | : | Access and Benefit Sharing |
| BDA | : | Biological Diversity Act 2002 |
| BMC | : | Biodiversity Management Committees |
| C.I.T.E.S. | : | Convention on International Trade in Endangered Species of Wild Flora And Fauna |
| CBD | : | Convention on Biological Diversity, 1992 |
| CBD | : | Convention on Biological Diversity |
| CIMAP | : | Central Institute of Medicinal and Aromatic Plants |
| CSIR | : | Council of Scientific and Industrial Research |
| DNR | : | Designated National Repository |
| DUS | : | Distinctiveness Uniformity and Stability |
| FAO | : | Food and Agriculture Organisation |
| FITM | : | Forum on India Traditional Medicine |
| GMO | : | Genetically modified organisms |
| GR | : | Genetic resources |
| IBAT | : | Integrated Biodiverstiy Assessment Tool |
| ICAR | : | Indian Council of Agricultural Research |
| IGC | : | Intergovernmental Committee |
| IGC | : | The Intergovernmental Committee |
| IPPC | : | International Plant Protection Convention |
| IPRs | : | Intellectual Property Rights |
| ISM | : | Indian Systems of Medicine |
| IUCN | : | International Union for Conservation of Nature |
| IUCN | : | International Union for Conservation of Nature and Natural Resources |
| L.P.C | : | Legal Procurement Certificate |
| LMO | : | Living Modified Organisms |
| MAP | : | Medicinal and Aromatic Plants |
| MoE&F | : | Ministry of Environment & Forests and Climate Change |
| NBA | : | National Biodiversity Authority |
| NBPGR | : | National Bank for Plant Genetic Resources |
| NBSAP | : | National Biodiversity Strategies and Action Plans |
| NGB | : | National Genebank |
| NMPB | : | National Medicinal Plants Board |
| NSTDA | : | National Science and Technology Development Agency |
| PGR | : | Plant Genetic Resources |
| SBB | : | State Biodiversity Boards |
| TCE | : | Traditional Cultural Expressions |
| TK | : | Traditional Knowledge |
| TRIPS | : | Trade-Related Aspects of Intellectual Property Rights |
| UNCTAD | : | United Nations Convention on Trade and Development |
| UPOV | : | Union for the Protection of New Varieties of Plants |
| WIPO | : | World Intellectual Property Organisation |
| WWF | : | World Wildlife Fund for Nature |

SCOPING PAPER

# Protection of Medicinal Plant Genetic Resources in India

This series of Scoping Papers presents a brief outline of the major components of studies that FITM undertakes. This Scoping Paper maps protection of medicinal plant genetic resources in international regimes and intergovernmental organisations, in national laws of select countries and in laws and policy initiatives of India. An in-depth study undertaken thereafter will analyse these international and domestic components with the objective of identifying issues that India must address internationally and domestically. This will facilitate in designing policy frameworks and appropriate responses during international deliberations at platforms such as WIPO IGC.

## 1. Introduction

The term 'Genetic Resources' (GRs) as defined by the Convention on Biological Diversity, 1992 (CBD) would mean any genetic material of plant, animal, microbial or other origin containing functional units of heredity that has actual or potential value.[1] Global biodiversity hotspots possess some of most abundant reserves of genetic resources and India is one such mega diverse country. With 17,000-18,000 flowering species, India contributes to 7 per cent of the world's biodiversity.[2] Of these nearly 8,000 species of medicinal plants distributed in 386 families and 2200 genera of flowering plants are the main source of raw drugs[3] utilised in Indian Systems of Medicine (ISMs). Over the past few years 10-18 per cent of total medicinal plant biodiversity (50,000 plants) has gained wide recognition in pharmaceutical industries. Besides, there is a growing demand for herbal products in India and abroad leading to an exponential growth in trade of plants, plant parts and value added products. Global market for herbal products is estimated to reach USD 5 trillion by 2050.[4] India is one of the major exporters of medicinal plants having exported USD 330.18 million worth of herbs during 2017-18 with a

This Scoping Paper has been prepared by Prof T.C. James, Visiting Fellow, Dr Krishna Ravi Srinivas, Consultant, and Dr Namrata Pathak, Research Associate, RIS.
The authors acknowledge with thanks the comments provided by Professor Sachin Chaturvedi, Director General, RIS and Dr T. P. Rajendran, Adjutant Fellow, RIS

growth rate of 14.22 per cent over the previous year.[5] India also exported value-added extracts of medicinal herbs / herbal products during 2017-18 valued at USD 456.12 million recording a growth rate of 12.23 per cent over the previous year.[6] The total domestic demand for raw herbal drugs itself, estimated at 5,12,000 MT for 2014-15, is expected to grow to 6,50,000 MT by 2020[7]. This growth in demand has not been matched with adequate supply. However, in the meanwhile Protection of medicinal plant genetic resources (PGR) has become imperative especially in the backdrop of increased unsustainable harvesting practices of plants collected from forests, promotion of cultivation of improved varieties of medicinal plants and cross border movement of Living Modified Organisms (LMOs) developed with the aid of biotechnology.

In keeping with increasing national and international demand of medicinal plants, the current procurement and supply practices has given rise to challenges of resource depletion. Of the total number of medicinal plants used globally, 21 per cent fall under the endangered category (Red List) of the International Union for Conservation of Nature (IUCN). IUCN updated the Red List in June 2015, and added forty-four Indian medicinal plants in the list where eighteen plants are categorized as vulnerable, sixteen as endangered and ten as critically endangered species.[8] Of the ten critically endangered species, namely, *Aconitum chasmanthum , Chlorophytum borivilianum, Gentiana kurroo, Gymnocladus assamicus, Lilium polypyllum, Saussurea costus, Tribulus rajasthanensis, Valeriana leschenaultia*, *Nardostachys jatamansi and Commiphora wightii,* most species are reported to be facing unsustainable collection practices and over harvesting leading to habitat loss.

Conservation of medicinal plant genetic resources (PGRs) is linked to its sustainable use. *In situ* and *ex situ* conservation programmes such as gene banks, regulations for sustainable harvesting and concepts of 'BioTrade'[9] and 'BioTrade Initiative' launched by international agencies like UNCTAD that aim to enable harmonisation of economic activities with conservation of biodiversity in trade of goods and services derived from biodiversity are some initiatives in this regard.

Protection and conservation mechanisms also include regulating access to resources for research, bio-survey and bio-utilization, commercial utilization, obtaining Intellectual Property Rights (IPRs), transfer of results of research and transfer of accessed biological resources. Access and Benefit Sharing (ABS) principles have been designed internationally through the Convention on Biological Diversity (CBD) and the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits from their Utilization to the Convention on Biological Diversity, and nationally through domestic laws regulating access to GRs.

PGRs have also been impacted by advances in biotechnology, i.e. the application of scientific techniques to modify and improve plants to enhance their value. The aid of biotechnology for development of a range of techniques for manipulating genomes has brought about a revolution in the way PGRs can be utilised. LMOs resulting from modern biotechnology, that may have adverse effects on biodiversity, is a subject of debate in medicinal PGR protection discussions. Genetically modified organisms (GMOs) emerging as potentially invasive species, threatening existence of traditional plant varieties, is a related area of concern. Therefore there is need for adequate level of protection in the field of safe transfer and handling and use of LMOs. 'Biosafety' mechanisms have been designed in national and international protocols (like the Cartagena Biosafety Protocol). Biotechnology research has also generated the debate on ownership of plant genes and genome intellectual properties. Governments of several countries, including India, have tried to shape their own policies to restrict patentability of plants, plant cells within the international framework wherever possible. At present the research paradigm of medicinal plant genome is still evolving.

## 2. Rationale for Present Study

Issues related to governance of PGRs have been studied extensively. Hawkes et al (2000) have studied several aspects of *ex situ* conservation of PGRs including history and management at global and local level.

Biber-klemm and Cottier (2006) have examined the international agricultural, environmental and trade laws from the angle of adequacy for preserving biological diversity and rights to PGRs and Traditional Knowledge (TK), but they have focussed more on subsistence farming and preservation of biological diversity. Similarly, De Boef *et al* (ed) (2013) have studied *in situ* conservation of PGRs through community biodiversity management. World Intellectual Property (WIPO)'s Technical Study on Disclosure Requirements in Patent Systems Related to Genetic Resources and Traditional Knowledge (2004) provides brief information about Intellectual Property Rights (IPRs) related jurisdictions on PGRs of several countries. Vivas-Eugui (2012) examines various issues raised in the WIPO Intergovernmental Committee (IGC)'s deliberations and makes recommendations regarding processes, substantive contents of existing research gaps in context of PGRs and Nagoya Protocol. Oldham *et al.* (2013) explore the interrelationship of human innovative activity and genetic resources.[10] Robinson *et al* (2017), one of the latest studies on deliberations at the World Intellectual Property Organisation (WIPO) Intergovernmental Committee (IGC) with reference to plant genetic resources, have examined the evolution and different perspectives of the discussion in the WIPO. Melendez-Ortiz and Sanchez (2005) study the interlinkages of biotechnology, trade and sustainability and the international and national instruments on biotechnology trade. Rajasekharan and Rao (2019) explore current state of conservation and utilization of horticultural PGRs (that includes medicinal plants), addressing contemporary approaches to conservation in connection with different technologies, including biotechnological approaches as practised in India and abroad. They also discuss legal aspects related to horticultural genetic resources and biotechnological aspects; and describes the key aspects of sustainable management and replenishment. Further Baruah (2015) and Singh & Peter (2018) have provided insights into the trends in R&D into high demand species, new forms of usage and brief outline of policies and initiatives for conservation and protection of PGRs in India. The Forum on India Traditional Medicine (FITM) Scoping Paper on "Protection of Traditional Knowledge in India (2018)[11]" maps protection of TK and associated PGRs. However, medicinal PGRs are largely included within the larger umbrella of PGRs and not studied independently. The inter-relationship of growing economic value of medicinal plants in domestic and international trade, the demand and supply gap of the same and emerging role of cultivation and genomics on IPRs related to medicinal PGRs have not been studied adequately. Consequently policy initiatives for protection and conservation of medicinal PGRs with reference to these developments have not been addressed sufficiently. There is also issue relating to the protection of TK relating to PGRs. Further, the IGC process is an ever evolving one and the drafts of the legal texts under its consideration also change based on the discussions in each session. Therefore, there is a need to study the latest text available with it and assess the same from the angle of practical policy making.

## 3. Scope

The paper intends to provide a brief overview of national and international instruments for protection of medicinal plant genetic resources and also the current state of discussions in the WIPO-IGC. Protection of PGRs associated with TK has been mapped in the Scoping Paper (No.2) on 'Protection of Traditional Knowledge in India'. This Scoping Paper maps protection of medicinal PGRs within the larger context of issues of conservation, IPRs, ABS and biosafety.

## 4. National Policies and Programmes

### Conservation

There are no separate policies or regulations targeting specifically *in situ* conservation of medicinal PGRs in the wild. Laws for protecting and conserving medicinal PGRs exist through forest laws and laws regulating access to biodiversity. Threat of habitat destruction is an important concern for medicinal plant protection. The Wild Life (Protection) Act 1972 ( amended in 2002), through a network of ecologically important protected areas, restricts carrying out any industrial activity inside these protected areas and co-

operative management through conservation reserve management committees and community reserve committees. Similarly, the Forest Conservation Act, 1980 (amended in 1988) regulates the de-reservation of forests or use of forest land for non-forest purposes without the prior approval of Central Government.

The Indian Council of Agricultural Research (ICAR) ICAR-National Bank for Plant Genetic Resources (NBPGR) houses the National Genebank (NGB) for *ex situ* conservation of PGRs. The national cryobank at NBPGR has the responsibility to conserve desiccation sensitive seeds, vegetative tissues, pollen and selected orthodox seed species. Presently 4,30,982 accessions belonging to 1547 species have been conserved at The National Gene Bank, including 5756 accessions of medicinal plant representing 412 genera and 578 species.[12] ICAR's Directorate of Medicinal and Aromatic Plants Research, under the National Agricultural Technology Project of Plant Biodiversity undertakes collection, evaluation, conservation and documentation of germplasm of medicinal and aromatic plants. Till date, 25 new improved varieties of medicinal plants of 14 species and seven varieties of aromatic plants of six species have been identified and released.[13] The Central Institute of Medicinal and Aromatic Plants (CIMAP) under the Council of Scientific and Industrial Research (CSIR) is engaged in medicinal and aromatic plant research, cultivation and business and work on improved varieties & agro-technologies, genetic improvement & breeding efforts, gene banks development and bio-village mission for cultivation and increasing productivity of medicinal and aromatic plants. The National Medicinal Plants Board (NMPB) undertakes a wide range of duties for medicinal plants conservation, inventorisation, and quantification of medicinal plants for commercial use[14]. Overall, India has adequate regulatory bodies for protection of medicinal PGRs through access control, gene banks, research and development for improved medicinal PGRs.

Several national policies with focused intervention for medicinal PGR conservation and protection exist. The National Forestry Policy (2016 draft)[15] provides for community participation at the *Gram Sabha* (Village Council) level for management of forests. The National Wildlife Action Plan 2017-2031 includes some key features such as conservation of threatened species of flora especially local endemics and highly traded species such as medicinal plants and orchids, and use of mobile technology to develop 'Digital Field Guides' for easy identification of various wildlife goods and their derivatives.[16] The National Environment Policy, 2006 calls for enhancing and conserving environmental resources which includes biodiversity (section 5.2)[17], and 'unlocking the value of genetic diversity', encouraging cultivation of traditional varieties of crops and traditional water conservation efforts, among others. It calls for harmonizing the Patents Act 1970 with the Biological Diversity Act 2002. Impact assessment of implementation of these policies on protection and conservation of medicinal PGRs has not been carried out.

## IPR Protection

IPR protection for medicinal PGR is important, particularly when high investment and strategic research are undertaken. IPR for medicinal PGRs emerges in two contexts, i.e. those found in wild and collected for use and those developed through plant breeding systems and used as cultivated Medicinal and Aromatic Plants (MAPs).

Protection of cultivated medicinal PGRs is to some extent ensured through the Plant Varieties and Farmers Rights' Act, 2001 and Rules 2003. The Act balances rights of breeders with traditional farming communities. It allows registration of three types of plant varieties, i.e. farmers' varieties, extant varieties and new varieties. Although most of the MAPs in cultivation are farmers' varieties, an instrument is available now to safeguard these varieties from piracy by registration. However, much benefit cannot be achieved in MAPs by the farmers because as per the Rules all the extant varieties are to be registered within the three years from the date of enforcement of the Act. According to the Act, extant varieties include farmers' varieties also. Under the Distinctiveness Uniformity and Stability (DUS) criteria, several

varieties of medicinal plant species have been included for registration. These include *Isabgol, Field Mint, Periwinkle, Brahmi , Damask Rose* and *Ashwagandha.*[18] The Act also provides for a National Gene Fund for promoting PGR conservation activities.

The Patents Act 1970 prohibits patenting of 'all methods of agriculture and horticulture or processes for the medicinal, surgical or other treatment of human beings'.[19] Plants and animals in whole or in part including seeds, varieties and species are also excluded from patentability under Act. As per the Patents Rules, 2003, a patent applicant has to disclose the source of the biological resource used in the invention and submit the permission of the competent authority to access the same. Nondisclosure of the source or geographical origin of biological material used for an invention in the complete specification also forms a ground for pre- and post-grant opposition as well as revocation of the patent.[20] Besides, Section 6(i) of the Biological Diversity Act, 2002 requires an applicant to obtain the approval of the National Biodiversity Authority (NBA) before applying for a patent for any invention based on biological resources obtained from India.

Under the Geographical Indications of Goods (Registration and Protection) Act, 1999 (GI Act) medicinal plants originating from particular regions often having distinct medicinal properties are eligible for registration and protection. The Act has established a GI registry [21] to facilitate registration of GIs in India. The number of products registered as geographical indications is 361 as of 20 September, 2019.[22] The number of medicinal plants registered has been negligible, though there are certain agricultural products like Navara rice, Ginger and Turmeric, which also have medicinal properties, perhaps due to lack of awareness among growers and collectors and the legal and financial costs associated with GI registrations.

IPR protection to medicinal PGRs under IPR laws in India has been subsumed under the larger scheme of PGR protection of plant and plant varieties. Also, IPR protection of medicinal PGR is often framed with reference to traditional knowledge of the same.

## Access and Benefit Sharing Provisions

Conservation and sustainable utilization of PGRs under the Biological Diversity Act 2002 (BDA) includes regulation of access to genetic resources including medicinal PGRs. Monetary and monetary benefit sharing mechanisms, regulation of transfer of research results based on Indian PGRs and establishment of Designated National Repository (DNRs) are some mechanisms to ensure implementation of access regime under the Act. The Biological Diversity Act 2002 and Rules, 2004 are the applicable legislations for access and benefit sharing on biological resources. For the effective implementation of the BDA, a three tier system has been established with National Biodiversity Authority (NBA) at the Centre and State Biodiversity Boards (SBBs) in each state and local level Biodiversity Management Committees (BMCs) functioning with municipalities and panchayats. In pursuance of the Nagoya Protocol, the NBA published the ABS guidelines in 2014 and the revised Draft Guidelines in 2019. The role of these agencies has been related to regulation of benefit sharing in the form of granting of approvals for access to biological resources and for applying for IPRs (the NBA), the granting of approvals for commercial utilisation , bio-survey and bio utilisation of biological resources (SBB) and preparation, and maintenance and validation of the People's Biodiversity Registers in consultation with the local people[23] (BMC). From 2006 till date (20 September, 2019), the NBA has granted approvals in 1068 cases ranging from access to bioresources for research to IPRs to third party transfer.[24] The approvals included 207 cases for access to biological resources for research or commercial purpose. The role of SBBs in determining terms of access and benefit sharing has been contested by many stakeholders and the process of redefining ABS guidelines is underway.

## Biosafety Provisions

The Environment (Protection) Act of 1986 regulates biosafety through the Regulations and Guidelines for Recombinant DNA Research and Biocontainment (2017).[25] A three tier mechanism, comprising

Institutional Biosafety Committees (IBSC) at the Institute/ company; the Review Committee on Genetic Manipulation (RCGM) in the Department of Biotechnology; and the Genetic Engineering Approval Committee (GEAC) in the Ministry of Environment & Forests and Climate Change (MoE&F) for granting approval for research and development activities on recombinant DNA products, environmental release of genetically engineered (GE) crops and monitoring and evaluation of research activities involving recombinant DNA technology, has been established under the Department of Biotechnology.[26] In one of the surveys conducted by MoE&F in 2014 under the Phase II Capacity Building Project on Biosafety, over 85 different plant species were identified as currently being used in experimental work, including plants used for food, livestock feed, fiber fuel and dietary or medicinal purposes. Brahmi was one such medicinal plant under the species undergoing experiment.[27]

## 5. International Regimes and Organizations on Medicinal Plant Genetic Resources

The exiting regimes have focussed on various aspects of PGR protection within the structure of property rights. From an environmental and conservationist perspective, protection of medicinal PGRs is addressed by the CBD and the voluntary Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization (Bonn Guidelines); and FAO's International Treaty on Plant Genetic Resources for Food and Agriculture. From an IPR and trade perspective, it is addressed by the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC) of WIPO; and the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) and the TRIPS Council of the WTO. The international regimes on PGR have also been influenced by domestic policies of states like US and EU.

The Convention on Biological Diversity, 1992 (CBD): Medicinal PGRs have not been explicitly on the agenda of various CBD meetings. However, CBD contains a large number of obligations for signatory countries that include *in situ* and *ex situ* conservation and incentives for biological resources that apply to Medicinal PGRs. The substantive provisions of the CBD with respect to ABS on PGRs are found in Articles 15, 16 and 19 of the Treaty. These include access to genetic resources, access to and transfer of technology and distribution of benefits arising out of research on biotechnology. In April 2002, (updated in 2010) the CBD adopted the Global Strategy for Plant Conservation which provides a policy environment that is appropriate for addressing the conservation challenges for MAP.[28] On biosafety, Article 19 deals with the distribution of benefits of biotechnology and at the same time recognises the need for establishing provisions for reducing potential risks to the environment and human health. The Cartagena Protocol on Biosafety (CPB) adopted in 2000 was evolved within the framework of CBD to regulate the risks of biotechnology.[29] The Protocol covers the transboundary movement, transit, handling and use of all LMOs which may have adverse effect on conservation and sustainable use of biodiversity.

*Nagoya Protocol:* While the CBD provided for, *inter alia*, the fair and equitable sharing of the benefits arising out of the sustainable utilisation of the genetic resources, it had not prescribed a detailed and mandatory mechanism for countries to ensure that the access to genetic resources from anywhere in the world is as per Prior Informed Consent (PIC) and ABS envisaged under the CBD. The Nagoya Protocol of 2010, which came into effect in 2014, mandated a disclosure of the genetic resources accessed and required countries to set up appropriate gate-keeping measures for the same.

*WTO TRIPS Agreement 1995:* The TRIPS Agreement sets minimum international standards for protection of IP rights. Article 27.3 (b) of the agreement, establishing minimum standards of protection in relation to inventions, indicates that Members may also exclude from patentability plants and animals and essentially biological processes for their production. The provision establishes that Members shall provide for the protection of new plant varieties – either by patents or an effective *sui generis* system or by any

combination thereof. Disclosure of Origin is also one of the proposals put forth by developing nations in the WTO. This includes introducing requirement on patent applicants to disclose origin/source of GRs as an amendment to Article 29.[30] Disclosure requirements are possibly the most visible form of user measures and are now mainstream in all ABS- and IP-related discussions and in various legal and regulatory frameworks.[31] Both developing and developed countries have adopted and incorporated forms of disclosure requirements, but implementation is still a challenge.[32]

As regards issues of plants being affected by risks involved with biotechnology, the Agreement on the application of Sanitary and Phytosanitary Measures (the SPS Agreement) of WTO recognises standards set by the International Plant Protection Convention (IPPC). It adopted guidelines for assessing potential risks to plants and plant products to protect plant and crop ecosystems from potential risks arising from introduction of LMOs.

*International Union for the Protection of New Varieties of Plants (UPOV) 1961:* The UPOV governs intellectual property rights of plant breeders. Plant breeders' rights can be used to misappropriate medicinal PGRs, as UPOV Secretariat holds that disclosure of origin cannot be an additional requirement for protection.[33] Biodiversity rich countries such as India and Thailand have opted to establish a *sui generis* system of plant variety protection outside of the UPOV framework. India is not a member of UPOV.

*WIPO:* The Intergovernmental Committee (IGC) on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore established under the WIPO in 2000,[34] provides a forum for negotiations on issues underlying development of binding international instruments on PGRs. Negotiations in the WIPO IGC on IP and TK, traditional cultural expressions (TCEs)/folklore and genetic resources have resulted in draft articles providing for three international instruments for the protection of TK, TCE, and the IP issues related to GR (IP/GR) respectively. The draft texts on these respective topics are heavily bracketed[35], indicating that the IGC Members are as yet not in agreement on a number of issues. The IGC draft text on genetic resources discusses, *inter alia*, defensive databases, a proposed mandatory disclosure requirement and intellectual property clauses calling for mutually agreed terms for access and equitable benefit sharing.[36] Many developing country delegations feel that the disclosure requirement is necessary to ensure traceability of PGRs used in an invention and to check whether there has been proper PIC and ABS agreement before accessing the same. As of now, the proposed disclosure Article talks only about the country of origin. At the same time, a bracketed Article 2 regarding objective says that the instrument is to prevent erroneous grant of patents. It is not yet clear whether disclosure requirements will form part of the treaty text finally emerging from the IGC, though disclosure is a requirement under the Nagoya Protocol. Patent systems like the International Patent Classification System and the Patent Cooperation Treaty, which are administered by the WIPO, have seen amendments.[37] The dramatic surge of patent activity for ethnobotanical medicines has led to the introduction of a new series of classification codes within IPC8 under A61K36 which replaced A61K35/78 from the 1st of January 2006.[38] The introduction of A61K36 has been accompanied by the inclusion of 203 sub-group classifiers which describe the family or genus. Additional indexing classifiers are also provided for the parts of plants involved.[39]

*Convention on International Trade in Endangered Species of wild flora and fauna (C.I.T.E.S.):* All CITES Appendix I & Appendix II plant species obtained from the wild are prohibited for export from India. Only cultivated/ artificially propagated plant species listed under Appendix II is allowed for export under cover of CITES export permit and Legal Procurement Certificate (L.P.C) or certificate of cultivation from the designated authorities.

*Food and Agriculture Organisation (FAO):* FAOs global system includes International Undertaking on Plant Genetic Resources. However, the Treaty focuses more on PGRs for food and less on PGRs for pharmaceutical or other industrial uses. Article 12.3(a) of the Treaty specifies that access to material under the multilateral system solely for purposes of

"utilization and conservation for research, breeding and training for food and agriculture", and excludes "chemical, pharmaceutical and/or other non-food/feed industrial uses."

*Biotrade Initiative:* Launched in 1996 by the United Nations Convention on Trade and Development (UNCTAD) to promote sustainable trade and investment in biological resources in line with the major objectives of CBD, i.e. conservation of biodiversity, sustainable use of its components and equitable benefit sharing from utilisation of genetic resources, the Biotrade initiative has reported sustainable management of 19 million hectares of land managed by beneficiary organisations promoting sustainable conservation and use of biodiversity.[40]

*International Union for Conservation of Nature and Natural Resources (IUCN):* IUCN engages with partner organizations in developing National Biodiversity Strategies and Action Plans (NBSAPs) , the main vehicle of national implementation of the CBD and other biodiversity related Conventions. IUCN's Red List of Threatened Species, World Database on Protected Areas (WDPA), Green List of Protected Areas, list of key biodiversity areas, Integrated Biodiverstiy Assessment Tool (IBAT), Global Invasive Species Database and IUCN Red List of Ecosystems are some knowledge products assisting biodiversity assessment .

*The World Wildlife Fund for Nature (WWF):* A major focus of WWF is germplasms conservation of economically important plants. This includes to a greater extent conservation of wild relatives of crops and to a lesser extent medicinal plants.

## 6. Protection of Medicinal PGRs in Select Countries

### Conservation Programmes

China's conservation programmes of medicinal PGRs: The Chinese government launched the overall plan of Chinese medicinal materials protection and development (2015–2020) in 2015. China had established 2729 nature reserves in approximately 1590 counties in mainland China by the end of 2014, including 428 national, 858 provincial and 1443 municipal nature reserves and covering approximately 14.8 per cent of its total landmass.[41] In Brazil, the National Center for Genetic Resources and Biotechnology—Cenargen, in collaboration with other research centers of Embrapa (Brazilian Agricultural Research Corporation), and several universities, has a programme to establish germplasm banks for medicinal and aromatic species.[42] Programmes/projects/activities on *in situ* conservation of Wild Crop Relatives and Wild Plants for Food and Agriculture have so far been poor in Bangladesh.[43] In Thailand, the Department of Agriculture undertakes research work on plant genetic resource (PGR) management and production technology aspects and collected herb and spice plants of about 1,500 species from five areas in different parts of Thailand. Twenty promising herbs have been identified for R&D efforts and presented a road map for the promotion of MAP species in Thailand (2014-19) which includes the promotion of MAP products for use in national drug industry and export, standardization of Thai products using Thai GAP and conservation of MAP genetic resources.[44]

### IPR Protection

Countries have adopted a wide range of practices and legal mechanisms under the flexibilities provided under Article 27.3 (b) of the TRIPS Agreement – regarding the specific subject of the patentability of plants. A number of countries have adopted statutory provisions excluding plants from patent protection, e.g., Andean countries (includes Peru) (Subsection (c) of Article 20 of Decision 486 of 2000).[45] A number of countries have excluded plant varieties from patent protection under statutory provisions, including China. The China Patent Office (SIPO) has issued guidelines that state transgenic plants obtained through biological methods like DNA recombination technology engineering belong to the category of "plant variety". Thus, in accordance with the provisions of Article 25.1 (4), no patent right is to be granted over them. Some countries exclude essentially biological processes for the production of plants. These include countries like Brazil, which does not consider it an invention. In South Africa, the Patents Act (57/1978) states that

a patent will not be granted for any variety of plant though new plant varieties are protected exclusively under the Plant Breeders' Rights Act (15/1976)[46]. However, genetically modified plants could be subject matter under the Patents Act as they are not strictly classed as new varieties of plants. In Bangladesh, plant varieties qualify to be protected by patents under the Patents and Designs Act, 1911.[47]

### Biosafety Laws

The Brazilian Biosafety Law (Lei No. 11.105) (24th March 2005) regulates use of genetic engineering techniques in, among others, environmental release and discharge of GMOs.[48] The law is administered by the national technical biosafety committee (CTNBio). South African Executive Council for Genetically Modified Organisms was set up in 1997 under the Genetically Modified Organisms Act (1997) as the responsible agency for authorising imports and release of GMOs.[49] In China agricultural GMOs are regulated by the 'Implementation Regulations on Safety Assessment of Agricultural GMOs, Implementation Regulations on Safety of Import of Agricultural GMOs and the Implementation Regulations on Labelling of Agricultural GMOs.[50] Peru's National Biosafety law (Law No. 27104) (1999) regulates prevention of risks derived from the use of biotechnology.[51] The law covers issues related to living modified organisms (LMOs) for the safe handling, transfer and use of LMOs.[52] In Thailand, the National Science and Technology Development Agency (NSTDA) and the Ministry of Science, Technology and Environment established the biosafety guidelines drafting committee in 1990[53], [54] . Biosafety in Bangladesh is governed by the Biosafety Rules of Bangladesh, promulgated under the Environment Conservation Act (1995) and published in the National Gazette in 2012.[55] These rules codify the regulatory structures and processes contained in the Biosafety Guidelines of Bangladesh (2008).[56]

### Access and Benefit Sharing Provisions

In South Africa the Biodiversity Act No. 10 of 2004, along with other regulations and the National Biodiversity Strategy and Action Plan regulate ABS implementation in the country.[57] Brazil's Provisional Act 2.186-16 enacts Articles 1, 8j, 10c, 15, 16.3 and 16.4 of the CBD by regulating: (i) access to components of genetic heritage existing within the national territory, on the continental shelf and in the exclusive economic zone, for the purposes of scientific research, technological development or bioprospecting; access to and transfer of technology for the conservation and sustainable use of biological diversity (Art.1). "Access" is not the same as "collection". The three categories of access activity covered by the Provisional Act are scientific research, technological development and bioprospecting.[58] In Peru, ABS requirements and procedures on ABS are outlined through two main instruments: : Supreme Decree 003-2009- MINAM on the Regulation on Access to Genetic Resources (2009) , Law 28216 on the Protection of Access to Biological Diversity and Collective Knowledge (2004) , Supreme Decree 035-2011-PCM on the Regulation of Plant Breeders' Rights (2011) and Supreme Decree 018-2015- MINAGRI on the Regulation for Forestry Management (2015).[59] China currently lacks a policy system for regulating ABS for its genetic resources.

## 7. Conclusion: The Way Forward

With growing trade in medicinal plants and value-added products, the demand and supply gap therein, the adequacy of existing instruments for conservation of these species needs to be assessed. With increasing efforts to cultivate medicinal plants as means to conserve PGRs, the interrelationship of modern biotechnology for plant breeding and rights of breeders within national and international policy framework becomes significant. Further, comparison of conservation efforts at the state, national and international is imperative for understanding of adequacy of policies for protection of medicinal PGRs. The in-depth study that follows will explore the following questions:

- Adequacy of: existing international instruments and policies for medicinal PGR protection; national governance and protection for medicinal PGRs and any subsequent recommendation for action policy; policy linkage from local and state level initiatives to national and international frameworks

on medicinal PGR protection and possible conflicts in centre -state jurisdictions over medicinal PGR protection;

- Mechanisms for balancing PGR protection with the needs of the AYUSH sector;
- Impact of modern biotechnology on medicinal PGRs protection; and
- Requirement of additional policies for medicinal PGRs protection.

## Endnotes

1 Convention on Biological Diversity, Article 2

2 National Medicinal Plants Board NMPB, Available at https://nmpb.nic.in/content/medicinal-plants-fact-sheet

3 Central Council for Research in Siddha Available at http://siddhacouncil.com/ccrs/wp-content/uploads/2018/10/03.pdf

4 WHO. 2009. *The Use of Herbal Medicines in Primary Healthcare.* Avaialable at http://apps.searo.who.int/PDS_DOCS/B4260.pdf

5 Press Information Bureau , Government of India, Ministry of Commerce & Industry, 7th January, 2019

6 Press Information Bureau , Government of India, Ministry of Commerce & Industry, 7th January, 2019

7 Goraya.G.S and Ved D.K. 2017. *Medicinal Plants in India : An Assessment of their Demand and Supply* , National Medicinal Plants Board and Indian Council of Forestry Research and Education p- vii

8 Central Council for Research in Siddha, Available at http://siddhacouncil.com/ccrs/wp-content/uploads/2018/10/03.pdf

9 Biotrade is defined as activities of collection, production, transformation and commercialisation of goods derived from native biodiversity under the criteria of environmental, social and economic sustainability(UNCTAD) .

10 Oldham P, Hall S, Forero O .2013. *Biological Diversity in the Patent System*. PLoS ONE 8(11): e78737. doi:10.1371/journal.pone.0078737

11 FITM, 2018. P*rotection of Traditional Knowledge in India.* Scoping Paper No. 2.

12 Gupta,V. 2018. *Indian Plant Genetic Resources of Medicinal Value in Peter K.V. and Singh Brahma* (ed) New Age Herbals: Resource, Quality and Pharmacognosy , Springer , Singapore

13 Available at https://dmapr.icar.gov.in/Research/CropImprovement.html

14 Available at https://www.nmpb.nic.in/content/functions-board

15 Available at http://www.moef.nic.in/sites/default/files/Draft%20National%20Forest%20Policy%2C%202016.pdf

16 Available at http://www.moef.nic.in/sites/default/files/NWAP%20-COMMENTS_0.pdf

17 National Environnent Policy 2006 , Available at http://www.moef.gov.in/sites/default/files/introduction-nep2006e.pdf

18 Available at http://plantauthority.gov.in/dus-center.htm

19 The Indian Patents Act 1970 (Section 3 (h))

20 Ibid, Subsection (j) of Sections 25 (1) and 25 (2) and Section 64 (1)(p) respectively

21 Geographical Indications Act 1999, Section 5 (1) and (2)

22 Registration Details Of Geographical Indications, Available at http://www.ipindia.nic.in/registered-gls.htm

23 Ibid, Rule 22 (6)

24 Available at http://nbaindia.org/content/683/61/1/approvals.html

25 Available at http://dbtindia.gov.in/sites/default/files/uploadfiles/Regulations_%26_Guidelines_for_Reocminant_DNA_Research_and_Biocontainment%2C2017.pdf

26 Available at http://dbtindia.gov.in/guidelines-biosafety

27 Ahuja V. 2018. R*egulation of emerging gene technologies in India.* BMC proceedings, 12(Suppl 8), 14. doi:10.1186/s12919-018-0106-0

28 Available at http://www.fao.org/3/Y4586E/y4586e08.htm

29 Available at https://bch.cbd.int/protocol/

30 Available at TN/C/W/59 – 2011 http://commerce.nic.in/trade/wtopdfs/tn-c-w-59.pdf

31 WIPO. 2017. *Key Questions on Patent Disclosure Requirements for Genetic Resources and Traditional Knowledge. Geneva: World Intellectual Property Organization (WIPO)*. Avaialble www.wipo.int/ publications/en/details.jsp?id=4194.

32 Manuel Ruiz Muller,2018. *Access to Genetic Resources and Benefit Sharing 25 Years on: Progress and Challenges , International Centre for Trade and Sustainable Development (ICTSD),* Issue Paper No.44

33 UNCTAD. 2014 T*he Convention on Biodiversity and the Nagoya Protocol: Intellectual Property Implications, A Handbook on the Interface between Global Access and Benefit Sharing Rules and Intellectual Property*

34 WIPO General Assembly (26th Session), 'Matters Concerning Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore' (Geneva, 25 September – 3 October 2000) WO/GA/26/6, paras 13–24.

35 PO/GRTKF/IC/34/5 , MARCH 15, 2017 , Thirty-Fourth Session Geneva, June 12 to 16, 2017 THE PROTECTION OF TRADITIONAL KNOWLEDGE: DRAFT ARTICLES http://www.wipo.int/edocs/mdocs/tk/en/wipo_grtkf_ic_34/wipo_grtkf_ic_34_5.pdf

36 UNCTAD.2014. *The Convention on Biodiversity and the Nagoya Protocol: Intellectual Property Implications, A Handbook on the Interface between Global Access and Benefit Sharing Rules and Intellectual Property*

37 Available at http://www.wipo.int/tk/en/tk/

38 Paul Oldham 2007. *Biodiversity and the Patent System: Towards International Indicators* Available at https://www.researchgate.net/publication/228177079_Biodiversity_and_the_Patent_System_Towards_International_Indicators

39 Paul Oldham 2007. *Biodiversity and the Patent System: Towards International Indicators* Available at https://www.researchgate.net/publication/228177079_Biodiversity_and_the_Patent_System_Towards_International_Indicators

[40] UNCTAD .2014. *Biodiversity and climate change: Integrating REDD+ into BioTrade Strategies* (UNCTAD/DITC/TED/2014/6) https://unctad.org/en/PublicationsLibrary/ditcted2014d6_en.pdf

[41] Xiulian Chi, Zejin Zhang, Xiaoting Xu, Xiaobo Zhang, Zhiping Zhao, Yining Liu, Qinggang Wang, Hui Wang, Ying Lia, Guang Yang, Lanping Guo, Zhiyao Tang, Luqi Huang,2017. *Threatened Medicinal Plants in China: Distributions and Conservation Priorities* , p-91 https://www.researchgate.net/publication/316503309_Threatened_medicinal_plants_in_China_Distributions_and_conservation_priorities/stats

[42] Roberto F. Vieira .1999. *Conservation of Medicinal and Aromatic Plants in Brazil* in J. Janick (ed.), Perspectives on New Crops and New Uses, ASHS Press, Alexandria, VA.

Available from: https://www.researchgate.net/publication/284250318_Brazilian_medicinal_plants_gene_bank [Accessed Aug 13 2019].

[43] FAO.2005. *The Second Report on Plant Genetic Resources for Foodand Agriculture of Bangladesh – The State of Activities* , FAOAG-GCP/RAS/186/JPNFIELD DOCUMENT NO.2007/05 http://www.fao.org/3/i1500e/Bangladesh.pdf

[44] Expert Consultation on Promotion of Medicinal and Aromatic Plants in the Asia-Pacific Region, 2013. *Proceedings Asia-Pacific Association of Agricultural Research Institutions (APAARI)Food and Agriculture Organization of the United Nations - Regional Office for Asia and the Pacific* (FAO RAP) http://www.apaari.org/wp-content/uploads/downloads/2014/10/Medicinal-and-Aromatic-Plants-Proceedings_21-10-2014-1.pdf

[45] Available at https://www.wipo.int/edocs/lexdocs/laws/en/br/br060en.pdf

[46] Available at https://www.upov.int/upovlex/en/profile.jsp?code=ZA

[47] Available at http://bdlaws.minlaw.gov.bd/print_sections_all.php?id=94

[48] Available at https://www.wipo.int/edocs/lexdocs/laws/en/br/br060en.pdf

[49] Genetically Modified Organisms Act, 1997 [No. 15 of 1997] - G 18029

[50] Melendeez-Oritz Richardo and Sanchez Vicente .2005.( Ed) *Development Perspectives on Biotechnology , Trade and Sustainability* , Earthscan , p-265

[51] Available at https://unep.ch/biosafety/old_site/development/Countryreports/PENBFrepEN.pdf

[52] Available at https://www.cbd.int/doc/newsletters/bpn/bpn-11-en.pdf

[53] In 2004, the Ministry of Science, Technology and Environment (MOSTE) was split and became the Ministry of Science and Technology (MOST) and the Ministry of Natural Resources and Environment (MONRE). All biosafety-related matters were then transferred to the MONRE

[54] Available at https://www.cbd.int/doc/newsletters/bpn/bpn-11-en.pdf

[55] Available at https://bangladeshbiosafety.org/wp-content/uploads/2017/11/Users_Guide_to_Biosafety_Regulatory_Process_Bangladesh_2017.pdf

[56] Available at https://bangladeshbiosafety.org/wp-content/uploads/2017/11/Users_Guide_to_Biosafety_Regulatory_Process_Bangladesh_2017.pdf

[57] Available at https://abs-sustainabledevelopment.net/country/south-africa/

[58] Available at http://www.abs-initiative.info/fileadmin//media/Knowledge_Center/Pulications/ABS_Dialogue_042014/National_study_on_ABS_implementation_in_Brazil_20140716.pdf

[59] Available at https://static1.squarespace.com/static/58bfcaf22994ca36885f063e/t/ 5b1699 2b352f539abbd558a5/1528207661061/UEBT-ABS-Peru-2016.pdf

## References


Baruah, Akhil. 2015. *Medicinal and Aromatic Plants,* EBH Publishers .India.

Biber-klemm S. and Cottier T. (eds). 2006. R*ights to Plant Genetic Resources and Traditional Knowledge: Basic Issues and Perspectives.* Swiss Agency for Development and World Trade Institute. (ISBN-13:978-0-85199-033-0)

De Boef, Walter Simon, Abishkar Subedi, Nivaldo Peroni, Marja Thijssen, Elizabeth O'Keeffe.2013. C*ommunity Biodiversity Management Promoting Resilience and the Conservation of Plant Genetic Resources*, Routledge, London.

Hawkes, J. G. N. Maxted and B.V. Ford-Lloyd. 2000. *The Ex Situ conservation of plant genetic resources*. Kluwer Publications

Meléndez-Ortiz, Ricardo and Sanchez, Vicente (ed). 2005. *Trading in Genes : Development Perspectives on Biotechnology*, Trade, and Sustainability. Earthscan, London

Oldham P. Hall S, Forero, O. 2013. *Biological Diversity in the Patent System*. PLoS ONE 8(11): e78737. https://doi.org/10.1371/journal.pone.0078737

Papadoupoulou Frantzeska. 2018. *The Protection of Traditional Knowledge on Genetic Resources.* Edward Elgar. (ISBN. 978 1 78643 742 6)

Rajasekharan P.E and V. Ramanatha Rao (ed). 2019. *Conservation and Utilization of Horticultural Genetic Resources*. Springer, Singapore

Robinson, Daniel F., Ahmed Abdel-Latif, Pedro Roffe.2017. *Protecting Traditional Knowledge: The WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore,* Routledge. London.

Vivas-Eugui, David. 2012. *Bridging the Gap on Intellectual Property and Genetic Resources in WIPO's Intergovernmental Committee (IGC) International Centre for Trade and Sustainable Development (ICTSD)*, Geneva http://www.ictsd.org/sites/default/files/research/2012/02/bridging-the-gap-on-intellectual-property-and-genetic-resources-in-wipos-intergovernmental-committee-igc.pdf

WIPO. 2004. T*echnical Study on Disclosure Requirements in Patent Systems Related to Genetic Resources and Traditional* Knowledge, https://www.wipo.int/publications/en/details.jsp?id=282&plang=EN

आयुष मंत्रालय
MINISTRY OF AYUSH
भारत सरकार Government of India

RIS
Research and Information System
for Developing Countries
विकासशील देशों की अनुसंधान एवं सूचना प्रणाली

## About FITM

The Forum on Indian Traditional Medicine (FITM), set up by the Ministry of AYUSH at RIS, is a platform aimed at contributing towards creation of pro-active strategies for promotion of Indian systems of medicine.

Among others, it supports studies on the issues pertaining to traditional medicines in India and countries that India could emulate from.

Core IV-B, Fourth Floor, India Habitat Centre Lodhi Road, New Delhi-110 003, India., Ph. 91-11-24682177-80
Fax: 91-11-24682173-74, Email: dgoffice@ris.org.in, Website: www.fitm.ris.org.in, www.ris.org.in

*Follow us on:*

www.facebook.com/risindia @RIS_NewDelhi www.youtube.com/RISNewDelhi