FITM
Forum on Indian Traditional Medicine

FITM POLICY BRIEF

Access and Expansion of Traditional Knowledge Digital Library and Incentivization of Innovations

Issues

- **Should research organizations be allowed to access TKDL with or without conditions?**
- **Should the scope of the TKDL be expanded?**
- **Should oral knowledge be included in the TKDL and allowed for access by research organizations?**

The patent controversy on neem and turmeric, the need for compliance with the global trade regimes, such as the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) and the international conventions like Convention on Biological Diversity (CBD), have necessitated development of mechanisms to protect Traditional Knowledge (TK) and other related sectors. Considering these, India has initiated legislative protection measures such as prohibition of inventions based on the traditional knowledge under the Patents Act, positive protection for traditional knowledge associated with biological resources through the Biological Diversity Act 2002 and the Protection of Plant Varieties and Farmers' Rights Act 2001. India also undertook requisite measures for defensive protection of TK through the development of a digital database of the TK available in India in the form of the Traditional Knowledge Digital Library (TKDL). In 2001, the Ministry of AYUSH established the TKDL in collaboration with the Council of Scientific and Industrial Research (CSIR)[1]; the latter is the implementing agency for the TKDL project. The TKDL is a collection of the medicinal formulations available in the ancient texts of Ayurveda, Siddha, Unani and Yoga. It is arranged in a patent- search friendly format, and is accessible in five international languages–

This Policy Brief has been prepared by Prof. T.C. James, Dr. Namrata Pathak and Ms. Deepika Yadav. The team acknowledges with thanks the contribution made by the participants at the 'Stakeholder Consultation on Traditional Knowledge Digital Library', organised by Forum on Indian Traditional Medicine (FITM) on 30th June 2017. The participants at the Consultation included representatives of the Ministry of AYUSH, Ministry of Commerce and Industry, TM industry, academia/research institutions, and practitioners of TM.

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English,Japanese, French, German and Spanish–with Information Technology tools, and is based on the innovative classification system–Traditional Knowledge Resource Classification (TKRC)[2]. It serves as an important source of information on prior art on the Indian systems of medicine. At present, the TKDL is accessible to 12 patent offices only[3] but other patent offices can seek access subject to the conditions laid down by the TKDL authority. The TKDL is considered a pioneer initiative to prevent misappropriation of the country's traditional medicinal knowledge.

… explore 'possibility of using TKDL for further R&D by private sector' …

The subject TKDL has been included in the National Intellectual Property Rights Policy 2016 (NIPR Policy 2016), announced by the Government of India in May 2016. The mandate of the policy is that the public research institutions should be allowed access to TKDL for furthering R&D as one of the ways to promote innovation. It also directs authorities to explore possibility of using TKDL for further R&D by private sector. This also proposes considering the possibilities of expansion of the ambit of the TKDL besides documentation of oral Traditional Knowledge (NIPR Policy 2016, Objective, 2.20, 2.19 and 2.21 respectively).

The implementation of the directives of the NIPR Policy 2016 for TKDL necessitates concerted action by the three Departments/Ministries of Industrial Policy and Promotion, AYUSH and Council of Scientific and Industrial Research (CSIR). What the policy seeks is not to restrict the utility of the TKDL merely as an important source of information on the prior art on Indian Traditional Medicines (ITMs) for the authorities examining patent applications to determine novelty as a basis for granting patents, but also to open it as a source of innovation, which is one of the objectives of both the NIPR Policy 2016 and the National Science, Technology and Innovation Policy 2012.

From the data available on the TKDL, it can be concluded that the TKDL has fulfilled its primary objective of preventing misappropriation of the traditional medicinal knowledge to a great extent through patenting. Since 2005, when the TKDL expert group estimated that approximately 2000 patents on knowledge available in the ancient texts of ITMs were being granted globally[4]; it could resolve 220 recorded cases of biopiracy[5].

The TKDL has been in existence now for more than ten years. In light of the experience of these years and also the new objective laid down in the NIPR Policy 2016, it is time to revisit parameters laid down for inclusion of data and access to the same. This Policy Brief would examine rationale for facilitating access to TKDL by public and private research organizations, as articulated in the NIPR Policy 2016, scope for expansion of the database, and chalk out conditions and safeguards to ensure its rightful utilization.

Drug Discovery, Innovation and Changing Policy Focus

Often a risky venture, new drug development - requires investments in R&D, and thereafter its clinical trials. India, although a world leader in generic pharma, has, hitherto, only played a limited role in new drug discovery. There is increasing recognition of the need for India becoming an innovation leader also. Hence, the current focus on R&D is

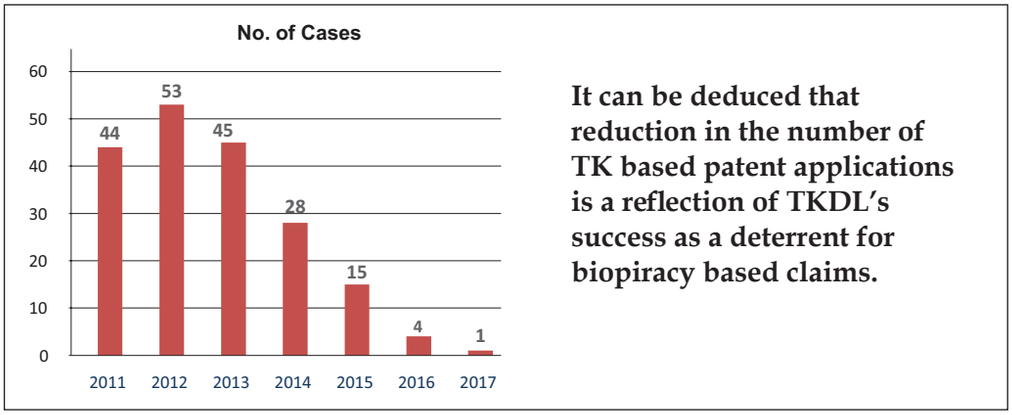
for new medicines, particularly for tropical diseases endemic to India. The R&D expenditure by the top pharmaceutical companies has shown a significant growth in India. The aggregate R&D expenses of the top seven companies increased at a CAGR of 26 per cent over FY 2011-16[6]. (see Figure 1)

The trend is towards expanding presence in speciality and complex therapy segments. Within drug related R&D, several factors indicate recent inclination towards mining AYUSH related systems. Discovery of cellular and molecular networks with complex interactions and regulatory mechanisms has caused mainstream (modern) medicine to shift its focus from a 'mono-molecular' or a single target approach to combinations and multiple target strategies[7]. In this context, Ayurvedic formulations as crude extracts become relevant, since such chemically complex formulations are likely to have multiple therapeutic actions[8]. With increasing volume of the pharmaceutical armamentarium, derived from natural world[9], the importance of TK related to biological resources has grown further. Besides, plant-derived compounds, to be used as drugs, are generally used in ways directly correlated with their traditional use as plant medicines[10].

In the context of a highly competitive pharmaceutical industry, the renewed interest in efficacy of TMs and the fast changing knowledge economy, a need for promoting of India's knowledge system along with its protection has arisen. The Knowledge Commission Report (2006-2009) had addressed the need for utilization of knowledge reserves like the TKDL[11], while the NIPR Policy 2016 is cautiously exploring possibilities of opening access to TKDL for private research organizations. One possible reason is the gainful utilization of India's TK systems for promotion of "high quality and cost effective innovation as a particularly Indian competence" (NIPR Policy 2016, Objective 1.2.4). The emphasis on the policy frameworks is on those diseases that are life-threatening and have a higher incidence in India; more specifically on their R&D related to prevention, diagnosis and treatment

Within drug related R&D, several factors indicate recent inclination towards mining AYUSH-related systems …

Figure1: Outcomes against biopiracy



It can be deduced that reduction in the number of TK based patent applications is a reflection of TKDL's success as a deterrent for biopiracy based claims.

Source: Council of Scientific and Industrial Research (CSIR), http://www.tkdl.res.in/tkdl/langdefault/Common/OutcomeMain.asp?GL=Eng (last visited 15th September 2017)

(NIPR Policy 2016, Objective 2.10). Utilization of existing knowledge sources, like those documented in the TKDL, would provide a window targeting towards these goals.

Moreover, mainstreaming of India's TM has been slower in growth in contrast to countries with comparable TM-base like China and Korea[12], which have surged ahead through planned and systematic mainstreaming of their traditional medicinal knowledge, both domestically and internationally. This includes making Traditional Chinese Medicine (TCM) databases available to the public for a fee[13]. While the impact of this arrangement on the knowledge-holders is uncertain, it must be admitted that it has the potential to promote innovations along with ensuring prevention of grant of patents on TK. In comparison, TKDL remains essentially a defensive mechanism to prevent persons from taking patents on existing formulations and processes[14], and it has yet to become a tool to facilitate innovation. The NIPR Policy's push for access to TKDL for public research institutions and its expansion to include other relevant TK systems is also to be seen in this context.

… mainstreaming of India's TM has seen a slow growth …

… commercialisation of Ayush-64,…and Ayush 82 …

Access to TKDL for Research and Development

On the access to medicines, a strong argument is being made in favour of delinkage i.e. separation of R&D cost of pharmaceutical and medical research from product price of medicines (given the high stated cost of drug development)[15]. Reforms in R&D systems ought to be more responsive to the needs of patients; considering exorbitant costs of R&D stated by some studies[16]. In this context, India enjoys comparative advantage *vis a vis* the developed nations with well qualified R&D personnel available at a lesser cost and 40-70 per cent lower running cost of operation and production[17]. To these can be added availability of knowledge systems, which provide further competitive advantage and potential for successful R&D on critical diseases if harnessed judiciously. Yet, India, despite being known as the pharmacy of the developing world, has played a negligible role in drug- related innovations using its ITM knowledge base. As compared to TCMs, the quantity and quality of scientific research on Ayurveda, Yoga, Siddha and Unani systems of medicine in India is limited[18]. An AYUSH Task Force report estimates that as compared to available TKDL data of 2, 97,183 formulations in Ayurveda, Siddha, Unani (ASU) texts, with more formulations being added regularly, only 500 formulations have been manufactured for contemporary practice [19] (See Figure 2). A large part of AYUSH research is supported by the five research councils catering to different components of AYUSH; research is mainly in-house (intramural).

For Public R&D Organizations

Since most of the R&D in the domain of the ITMs is in the public sector, giving them access to the TKDL is likely to reduce cost of drug discovery. The argument for access to TKDL is based on the need for fulfilling public health priorities as is laid down in the NIPR Policy 2016 and National Health Policy (NHP) 2017 through these, hitherto, underutilized knowledge resources. Since ITM formulations are for

diseases that affect Indian population, utilization of these formulations by the public research institutions would help provide solutions for these health priorities.

For Private Research Organizations and Start-ups

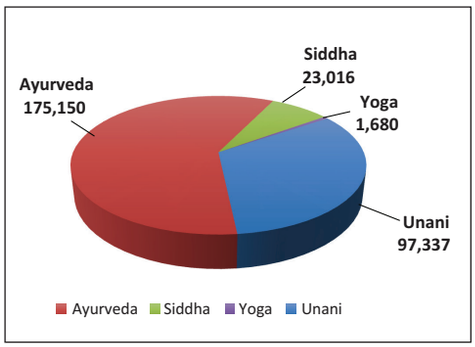
The role of private research organizations in AYUSH research is even more limited as compared to public research organizations. Within the private sector, no new drug has been tested and commercially marketed out of research in the recent years.[20] One of the reasons offered is that it is too expensive and time-consuming to be profitable[21]. The process of drug discovery whether in the traditional medicine or in the modern medicine, is estimated to take on an average 10 years, and cost can be more than 800 million dollars[22] with only one in 5000 lead compounds successfully advancing through clinical trials to be approved for use.[23] The ITM industry in India is further impinged by its size, which barring a few large pharma companies, are mostly SMEs, with limited financial capability for R&D. However, there exists substantial potential for growth in the sector. As per the records of the National Medicinal Plant Board (NMPB), herbal industry may increase to Rs 80-90 billion by 2020[24]. From the perspective of this industry, there would be immense advantage of access to TKDL as it would reduce transaction cost and accelerate speed of the industry to come up with new products by taking lead for innovations and formulations from the TKDL. This would also serve to promote start-ups in the industry as the known utility of the formulations mentioned in the TKDL would reduce risks associated with developing new products based on such knowledge.

Joint Research by Public and Private Sectors

With sufficient safeguards in place, access to TKDL can also initiate/ create scope for joint research by private and public sectors. The NHP 2017 aims to promote drug innovation and discovery through public investment in priority research areas with greater coordination and convergence between drug research institutions, drug manufacturers and premier medical institutions (NHP 2017, para 25.2). However, given the current profile of pharma research, both globally and in India, private sector can play a major role in scaling up research in critical areas. To make 'full use of all research capacity of the nation' (NHP 2017, para 25.1) it is necessary to encourage and incentivize private sector. In this regard, the scheme for extra mural research in AYUSH already envisages funding private research institutions.[25] This kind of PPP is being witnessed in certain

Access to TKDL would be justified only with value addition that it makes to public good sustainably …

Figure 2: Formulations Transcribed in TKDL (over 2,97,183)



Source: Council of Scientific and Industrial Research (CSIR), http://www.tkdl.res.in/tkdl/langdefault/Common/SourceInfo.asp?GL=Eng (last visited 15th September 2017)

areas. For example, the National Research Development Corporation (NRDC) under the Ministry of Science & Technology and Dabur India, have entered into license agreements for commercialization of Ayush-64, an Ayurvedic formulation for treating malaria, and Ayush-82, for management of diabetes. Both the formulations have been developed by the Central Council for Research in Ayurvedic Sciences, an autonomous body under the Ministry of AYUSH.[26] Taking a step further, the opening up of the database may also fulfil the objective of leveraging international research collaborations involving nations of the Global South to build domestic institutional capacity in green-field innovation and for knowledge and skill generation (NHP 2017, para 25.4).

… fee to be estimated on the basis of the quantum of data exported and number of searches …

A PPP model of public funding to a private research organization, where research results are shared equally between the partners can be a way to incentivize ITM research. Allowing access to TKDL would be beneficial to students and researchers who focus on national priority areas such as energy and food security, healthcare and agriculture as well as specific sectors like biotechnology. Access to TKDL under the 'knowledge commons'[27] by encouraging R&D including open source based research such as the Open Source Drug Discovery (OSDD) of the CSIR for new inventions for prevention, diagnosis and treatment of diseases, especially life threatening and having high incidence in India (NIPR Policy 2016, Objective 2.10) would provide another rationale for gainful utilization of TKDL database. Access under such conditions would be a great motivator for pharmaceutical R&D, paving way for greater innovation and access to medicines.

Conditions for Access

The nature of traditional knowledge, as already existing knowledge but seeking intellectual property protection for itself, presents certain challenges for granting access to the knowledge database. The issues of equity and justice are raised by many in the context of possible commercialization of the results of such access. Arguments are advanced to the effect that the preservers of the knowledge deserve benefit sharing when access is given, which may lead to commercial advantage to the accessor, if allowed. Further, since many of the knowledge holders had concerns regarding uncontrolled access, as the knowledge itself being cultural heritage, allowing access to TKDL should come with more stringent conditions than applied to any other knowledge source. Any consideration of access also comes with a responsibility of preventing the dilution of the mandate of the TKDL; especially when providing access to private sector research initiatives. Thus, a cautious approach that includes opening access to TKDL progressively, in a phased manner, starting with public institutions and then extending slowly to private institutions, with conditions, would be a safer option.

Since TKDL has not been made accessible to the public till date, an access regime for the same has not yet been devised. Ensuring safeguards would, therefore, have to be negotiated thoroughly with inclusion of conditionalities in contracts and licensing of information accessed. The nature of the activity for which access is sought may be one determinant

for access to TKDL for public and private use. The NIPR Policy 2016 and the NHP 2017 envisage R&D of ITMs with focus, *inter alia*, on public health; hence access to data for priority health related knowledge to public research institutions augurs well as a determinant for access to TKDL. This condition, if applied to the private sector research, would further strengthen the case for appropriate use of the TKDL. The objective of public good rationalises the grant of access. An inclusion of the public health access clause where every innovation from TKDL database must be available at government hospitals and public health centres before commercialization can justify the access. The access regime should also have provisions for evaluation of its effectiveness, transparency and non-discrimination.

The application of Ostram's law[28] that justifies sharing of useful resources among individuals but with conditions imposed on the usage of such resources to prevent their inevitable depletion provides another applicable safeguard. The habitat loss by export of medicinal plants collected from wild sources has already led to notification of 29 species as banned for export. The list contains some popularly used drugs in strong sustainability clause as the access to TKDL should be proportionately linked to the access to the genetic and biological resources. Hence, access to TKDL, including by private research organizations, would be justified only with the value addition that it makes to public good sustainably and with safeguards to prevent misappropriation.

Monetary Fee

The TKDL is not a commercial entity and as of now has no provision for any access fee. If access is being considered then the levy of monetary fees on the lines of Access and Benefit Sharing (ABS) under The Biological Diversity Act 2002 (BDA) and its Rules can be considered. These provisions are in line with the principles laid down in the CBD. This argument is based on the grounds of certain similarities between biological resources and TK and also the close affinity between the two as recognized under the BDA by the following expression ' biological resources and associated traditional knowledge'. The Bonn Guidelines[29] under CBD elaborate on ABS arrangements 'by identifying steps involved in the process of obtaining access to benefit sharing', including monetary and non-monetary benefits and requirement of 'prior informed consent' (PIC), among others. The Nagoya Protocol (2010)[30] further provides the terms by which benefits (monetary and non- monetary) arising out of such usage are to be shared in an equitable manner through arrangements such as royalties and joint ventures. As a signatory to the CBD and the Nagoya Protocol, access to TK through TKDL also implies need for incorporation of the provisions of the above. Fortunately for India, the BDA and its Rules provide for implementation of the ABS and other access related conditions such as PIC. The benefit sharing as envisaged by the National Biodiversity Authority (NBA) includes both monetary and non-monetary provisions such as joint ownership of IPRs, transfer of technology, setting up of venture capital fund, etc. One of the hindrances associated with the ABS is the valuation of TK; given its intangibility. One option is for the

… keeping their knowledge in oral format only to preserve control and also to prevent misappropriation…

fee to be estimated on the basis of quantum of data exported and number of searches. However, it needs broader deliberations about techniques of monetisation of non-monetary ABS sharing especially of natural resources with TK value. A mechanism similar to the National Biodiversity Fund (NBF) under the BDA where the monetary fee is levied by the NBA as depository for access to biodiversity resources can be devised for the TKDL access fee, with the revenue so generated to be utilized for further public health research. The mode of ABS of the TKDL to be negotiated under this arrangement, however, would necessitate coordination between the TKDL Authority and the NBA, which administers ABS provisions under BDA. The governance of TKDL's ABS mechanism as per this arrangement may prove efficient under a *sui generis* provision.

Expansion of the Scope of TKDL

Given the current pace of innovation in ITMs, any encouragement, including using TKDL as a tool for such ends is to be welcomed. This does not dilute TKDL's utility as a tool against biopiracy. Its presence in public domain and availability for R&D, both by public and private organizations may even enhance the status of India's traditional medicinal knowledge as a prior art. Hence, the NIPR Policy 2016 has proposed consideration of expanding the scope of TKDL. The library, till date, has data on Ayurveda, Siddha, Unani and Yoga available on the codified/written texts only. Suggestions on expansion of the scope of TKDL include all forms of traditional knowledge, namely, medicines, intangible cultural heritage, non-codified manuscripts, diets and recipes and their medicinal properties, as described in ancient texts on treatment of physical and mental ailments, diagnostic methods, cosmetics and cosmeceuticals, agriculture, architecture and design. Many knowledge holders have been keeping their knowledge only in oral format to preserve their control and also to prevent misappropriation and misuse of that knowledge. All sensitivities and concerns would have to be addressed when documenting such knowledge and providing access of the same. Documentation of oral TK by introducing PIC from knowledge holders, and MoUs, including joint patent and publication ownerships in case of public and private collaborations, could be some of the mechanisms to ensure benefit-sharing with the custodians of this knowledge.

Conclusion

India's emphasis on promoting the AYUSH sector through innovation, R&D and mainstreaming the same in public health practices have had a slow start. It has, however, received a major impetus in the recent years with efforts to explore possibilities of utilization of knowledge systems like those documented in the TKDL for achieving these objectives. While countries like China and Korea have successfully developed TK databases which have been made available in public domain, enabling innovators to find potential sources for new drugs, India is seeking to explore the option of opening access to its TKDL only lately, although it was a pioneer in creating TK digital database. Exercising this option, however, will have to be done in a phased manner, first allowing access to public research organizations and later to private research organization with certain conditionalities. There is also the need to expand the scope of TKDL to include

KEY FINDINGS

1. Benefits for public research institutions

- Contribution to the development of affordable drugs, relating to neglected diseases (NIPR Policy 2016, Objective 2.9)
- Support for R&D, including open source research such as the Open Source Drug Discovery (OSDD) of the CSIR (NIPR Policy 2016, Objective 2.10)
- Promotion and integration of TK with modern health system in conjunction with objectives of the National Health Policy 2017 (NHP 2017).
- Research augmentation support in light of negligible drug discovery by public research institutions.
- Promotion of Indian traditional medicine (ITM) and its efficacy.

2. Benefits for private R&D institutions

- Reduction in cost of R&D (by providing leads), resulting reduced cost of medicines.
- Invigoration of innovation both in modern and traditional medicine industry.
- Expansion of scope of joint research by private and public sectors.
- Promotion of start-ups in traditional medicine sector by reducing risks on investments.

3. Conditions and safeguards for access

Access to be negotiated through contracts and licensing.

- Opening TKDL progressively, in phases, beginning with access to public institutions.
- The nature of the activity would determine access with data on priority health related knowledge to public research institutions to be facilitated in initial stages.
- IPR that may result from the R&D by private institutions need to be specifically addressed in safeguard measures.
- The nature of commercialization of the products developed using the TKDL needs to be determined as a part of the conditionality for access.
- Access and benefit sharing mechanisms can be similar to those in The National Biological Diversity Act 2002 and may include both monetary and non-monetary benefits.

4. Expansion of the ambit of TKDL

- Since much of the formal knowledge associated with TK in Ayurveda, Siddha, Unani and Yoga has been documented, the need has been felt for including other hitherto neglected knowledge systems. These include knowledge associated with diets and recipes, their medicinal properties, diagnostic methods, Indian psychology, cosmetics and cosmeceuticals, as studied under the traditional medicinal knowledge systems.
- Other fields of traditional knowledge to be included in the TKDL can be Indian agriculture, architecture and design.

5. Documentation of Oral TK

- Absence of documented proof of oral TK in the IPR regime, which requires documentary proof of prior art, to challenge wrongful claims has necessitated its inclusion in the TKDL. Propriety rights attached with ownership of oral TK, however, make documentation itself a challenge.

all traditional medicine knowledge in the country including oral knowledge. However, the continuing likelihood of misappropriation of TK through patenting and other IPR activities by unauthorized persons/entities do require continuation of the TKDL as a means for defensive protection of Indian TK.

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Research shaping development agenda

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The focus of the work programme of RIS is to promote South-South Cooperation and collaborate with developing countries in multilateral negotiations in various forums. RIS is engaged across inter-governmental processes of several regional economic cooperation initiatives. Through its intensive network of think tanks, RIS seeks to strengthen policy coherence on international economic issues and the development partnership canvas.

For more information about RIS and its work programme, please visit its website: www.ris.org.in

About FITM

The FITM has been established in the RIS with the participation of the Ministry of AYUSH as a common platform for all actors and stakeholders to contribute to pragmatic policy-making in the area of Traditional Medicine (TM) and Traditional Knowledge and to develop pro-active policies and strategies. The broad objectives of the FITM are to: undertake/ commission studies on various issues pertaining to Indian TMs, IPRs and regulatory frameworks for traditional medicinal knowledge; examine trade policy with reference to TMs; prepare cogent and coherent policy and strategy responses on emerging national and global developments; provide critical inputs such as policy briefs, briefings and reports to the Government of India in a continued and sustained way; and to facilitate interactions with experts and stakeholders and policy-makers from India and abroad. It would also provide Fellowships and Scholarships for studies in the area of TMs, arrange invited talks by national and international experts, and organize periodic consultations.

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

Core IV B, 4th Floor, India Habitat Centre, Lodhi Road
New Delhi-110003, India, Ph.: 91-11-24682177-80
Fax: 91-11-24682173-74, Email: dgoffice@ris.org.in
Website: http://www.ris.org.in

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