

Report
on
Steps to be taken by
Government of India
in the context of
Data Protection Provisions
of
Article 39.3 of TRIPS Agreement

Mrs Satwant Reddy

Secretary
Department of Chemicals & Petrochemicals
Ministry of Chemicals & Fertilizers
Government of India

Mr Gurdial Singh Sandhu

Joint Secretary
Department of Chemicals & Petrochemicals
Ministry of Chemicals & Fertilizers
Government of India

31st May, 2007

CONTENTS

Acknowledgements.....	i
Executive Summary.....	iii
1. Introduction.....	1
2. Important issues related to Data Protection.....	7
3 Indian Legal Framework with respect to Data Protection in TRIPS.....	13
4 Current State of Data Protection across different countries.....	23
5. Registration Data requirements for Agrochemicals and Pharmaceuticals.....	24
6. Possible Alternatives.....	28
7 Recommendations.....	39
Annexure-1 Copy of the O M constituting the Inter-Ministerial Committee	54
Annexure-2 Views of Dr. N.S. Gopalakrishnan Along with proposed amendments in Drugs & Cosmetics Act / Rules	55
Annexure-3 Proposed Structure of Central Drug Authority	58

Acknowledgements

Preparation of this report has involved numerous rounds of discussions and interactions with a large number of stakeholders and experts in the field.

We would like to thank Mr Vinay Kohli and Mr Pratyush Sinha, former Secretaries to Government of India, Department of Chemicals & Petrochemicals (DCPC) who initiated the process of dialogue with various stakeholders and experts on this issue. We would also like to thank Mr Gopal Pillai, Commerce Secretary, Mr A.K. Dua, Secretary Department of Industrial Policy and Promotion, Mr P.K. Hota, former Health Secretary, Dr R.A. Mashelkar, Secretary, Department of Scientific and Industrial Research, Mr Arvind Virmani, Principal Advisor, Planning Commission along with their team of officers who have been helping us with their views from time to time. Thanks are also due to Mr K.C. Misra, Joint Secretary, DCPC, Joint Secretaries and Directors of Departments of Commerce, DIP&P, Health, DST, DBT, Legal Affairs and AYUSH and other experts Mr Praveen Shroff, M/s Amarchand Mangaldas and Suresh Shroff & Co., New Delhi, Mr Ashwini Kumar, former Drug Controller General (India), Mr Y. Tsering, Secretary, Central Insecticides Board who have been participating as members of the inter-ministerial Committee to assist us in formulating the approach towards data protection.

Our special thanks to Dr N.S. Gopalakrishnan of Centre for Intellectual Property Rights Studies, Cochin University, Kerala, M/s Anand and Anand and M/s Corporate Law Group, leading law firms for providing us their views and analysis on this subject.

We would also like to acknowledge the contribution of representatives of pharmaceuticals and pesticides industry in providing us with their views and assessment as well as all the necessary inputs for the report. Mr D.G. Shah, Secretary General, Indian Pharmaceutical Alliance (IPA), a group of top pharma companies in India and Mr P.K. Majumdar, Chairman Emeritus, Crop Life India, Mr Partho S. Lahiri, Chairman, Crop Life India, Dr Uttam Gupta, Resident Director, Crop Life India, Mr Salil Singhal, Chairman Emeritus, Crop Care Federation of India (CCFI), Mr RG Agarwal, President CCFI and Mr P. Dave, President, Pesticides Manufacturers and Formulators Association of

India(PMFAI) and Mr. Rajju Shroff, CMD, United Phosphorus Ltd. have contributed with their views on the subject.

We would also like to thank former officers in the Department of Chemicals and Petrochemicals, in particular Mr Sharad Gupta and Mr R.I. Singh, former Joint Secretaries, Mr Arvind Singh and Mr Gurdeep Singh, former Directors and Mr Paresh Johri, Deputy Secretary (now under training) for taking the process forward.

We acknowledge the assistance provided by Dr Biswajit Dhar, Professor and Head, Centre for WTO Studies, IIFT, New Delhi in the form of his expert views and for assisting in the editing of the report .

(Gurdial Singh Sandhu)
Joint Secretary to Govt. of India

(Satwant Reddy)
Secretary to Govt. of India

New Delhi, the 31st May, 2007

Executive Summary

After the Agreement on Trade-Related Aspects of Intellectual Property Rights, commonly known as the TRIPS Agreement, the issue of data protection has assumed considerable importance. In fact, it has been one of the most debated aspects of TRIPS due to the ambiguous nature of some of its provisions particularly Article 39.3. As a result, implementation of Article 39.3 by various countries is not uniform.

The Department of Chemicals and Petrochemicals (DCPC), Ministry of Chemicals and Fertilizers, Government of India was entrusted with the task of suggesting measures to be adopted in the context of data protection provisions outlined in Article 39.3 of TRIPS. This was a complex task due to different interpretations made by different stakeholders both within and outside India regarding the obligations of a member country in implementing these provisions. In the context of India, there is a need to strike a balance between the needs of the public for access to affordable medicines and the requirements of pharma industry to generate revenues for R&D.

An Inter-Ministerial Committee was constituted on 10th February, 2004 to assist the DCPC to act as a Consultative Group and recommend appropriate measures in this regard. The following specific issues were for consideration of the Department:-

- a) Steps to be taken in the context of Article 39.3 of TRIPS Agreement,
- b) Whether data protection can be offered under the existing legal provisions or an appropriate new dispensation is required.

The Inter-Ministerial Committee held several meetings with representatives of concerned departments and experts in the field. Meetings were held with various groups/ delegations from industry, non-government bodies and other interested persons. These meetings helped to narrow down the differences among the stakeholders to some extent, although some differences still persisted.

India has emerged as one of the important producers of generic medicines in the world. There has been a prolonged debate on the likely impact of data protection provisions on the growth of industry and on availability of cost generic medicines.

It was noticed that there was enough flexibility in the provisions of TRIPS Agreement for a country to determine appropriate means of protecting test data. In terms of paragraph 4 of the Doha Declaration, the provisions are to be *“interpreted and implemented in a manner supportive of WTO Members’ right to protect public health and, in particular, to promote access to medicines for all”*. Hence the approach to be adopted should use the flexibilities in TRIPS Agreement, keeping in view the national interest of the country.

In India, there is no separate legislation to protect the undisclosed test data in case of pharmaceuticals and agrochemicals submitted to the regulatory authorities. The protection to undisclosed information or trade secrets against unfair competition is provided through the provisions of Common law, Law of Torts and the Indian Contract Act, 1872. For breach of contract, remedies are available under the Indian Contract Act, 1872 by way of compensation and injunction. Some courts have followed the common law principles to protect trade secrets but there is no express case law creating obligations on the part of the Government agencies to maintain confidentiality based on common law. Section 5 of the Official Secrets Act provides that unauthorized disclosure of official secrets is a punishable offence. This provision is also applicable to government employees.

The Drugs and Cosmetics Act, 1940 regulates manufacture and marketing approval of drugs and traditional medicines while The Insecticides Act, 1968 deals with the agricultural chemicals (insecticides, fungicides and weedicides). Both Acts require submission of valuable test data to establish safety and efficacy of new drugs and agricultural chemicals before grant of marketing approval for them.

During deliberations, it was realized that data requirements for registration of agro-chemicals differ considerably from those for pharmaceuticals. Several countries have accepted the difference and have made different provisions for regulating the protection of safety and efficacy data for the two sectors. Similarly due to wide differences between

pharmaceuticals and traditional medicines, there is a need to consider separate dispensation for them as well.

Looking to the different nature of data requirements for Agro-Chemicals, Traditional Medicines and Pharmaceuticals, it is considered proper to recommend different approaches for these three types of products. As regards agro-chemicals and traditional medicines, the approach recommended is data protection for a fixed period of three years and five years respectively, with the Regulator not relying on the data submitted by the Originator while granting marketing approval on second and subsequent applications.

In so far as pharmaceuticals are concerned it is recommended that a calibrated approach with a transition period would be in the interest of the country. The system of data management in the office of Drug Regulator should be improved with the help of technology and best products adopted elsewhere. The initial steps to be taken should be to implement the minimum standards of data protection i.e. presentation of unauthorized disclosure and unauthorized use through explicit legal provisions in the Drugs and Cosmetics Act, 1940 and the Insecticides Act, 1968 and the Rules framed under these. Liability of the third parties in case unauthorized use of test data of the Originator should be made explicit in these laws and it should be enforceable through courts. Simultaneously the regulatory system should be strengthened to equip the Drug Regulator (DR) with in-house multi-disciplinary expertise for examination of the vast scientific and technical data that would be submitted by the innovators seeking marketing approval. There is no need for separate statute for data protection in India.

In the past, transition period, higher standards of data protections can be considered for adoption. This may include a fixed period data protection for a period of five years with non-relatively the Drug Regulator in the data submitted Originator. Several safeguards have also been suggested to take care of any adverse effect on public health or situations of health emergency. The duration of the transition period as well as the modern needs to be discussed further before any decision to adopt is taken.

Recommendations made are enumerated in Chapter 7 of the Report.

This Report on the one hand takes into account the minimum requirements envisaged in the article 39.3 of TRIPS which need to be incorporated in the legal and regulatory system in an explicit manner but also what would be in the best interest of the country at the present time as well as in the future.

Chapter-1

1.0 Introduction

At the instance of the Department of Commerce, the Department of Chemicals and Petrochemicals, Ministry of Chemicals and Fertilizers, Government of India was entrusted with the task of suggesting measures that should be adopted in the context of data protection provisions as outlined in Article 39.3 of TRIPS. This was a complex task due to varying interpretations made by different stakeholders, both within and outside India regarding the obligations of a member country in implementing these provisions. In order to assist the Department in suggesting appropriate measures to be taken in this regard, an Inter-Ministerial Consultative Committee was constituted on 19th February, 2004. The following specific issues were for consideration of the Department:–

- a) Steps to be taken in the context of Article 39.3 of TRIPS Agreement.
- b) Whether data protection can be offered under the existing legal provisions or an appropriate new dispensation is required.

1.1 Article 1.2 of the TRIPS states that the term intellectual property refers to all categories of intellectual property that are the subject of Sections 1 to 7 of Part II. Section 7 of PART II is entitled “Protection of Undisclosed Information” and includes Article 39.

1.2 Article 39 of TRIPS comprises Articles 39.1, 39.2, and 39.3

For a full appreciation of the scope and spirit of Article 39.3, it should be read in conjunction with Article 39.1 and Article 39.2.

Article 39.1 states:–

“In the general course of ensuring effective protection against unfair competition as provided in Article 10 bis of the Paris Convention¹ (1967), Members shall protect undisclosed information in accordance with paragraph 2 and data submitted to governments or government agencies in accordance of paragraph 3.”

¹ Paris Convention (1967 refers to the Stockholm Act of this Convention of 14th July, 1967).

Article 10 bis of the Paris Convention was the first attempt to protect trade secret at the international level. Based on common law principles, the treaty obligates member countries to protect trade secrets from unfair commercial exploitation. Though there was no express provision to protect test data submitted to regulatory authorities under this Article, it was interpreted by many countries that the Common law principles of trade secret protection will extend to test data as well. Some countries did protect test data on this obligation following the common law principles.

Article 39.2 states:-

“Natural and legal persons shall have the possibility of preventing information lawfully within their control from being disclosed to, acquired by, or used by others without their consent in a manner contrary to honest commercial practice so long as such information:

- **is secret in the sense that it is not as a body or in the precise configuration of and assembly of its components, generally known or readily accessible to persons within circles that normally dealt with the kind of information in question**
- **has commercial value because it is secret; and**
- **has been subject to reasonable steps under the circumstances, by the person lawfully in control of the information to be kept secret.”**

For the purposes of this provision, “ a manner contrary to honest commercial practices” implies practices such as breach of contract, breach of confidence and inducement to breach, and includes the acquisition of undisclosed information by third parties who know, or were grossly negligent in failing to know, that such practices were involved in the acquisition.

Article 39.3 of the TRIPS Agreement mandates protection for the test data submitted by the pharmaceutical and agro-chemical industries for market approval. It sets the minimum standards in this regard and reads as follows:

“Members when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the

origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use.”

1.3 According to the TRIPS Agreement data protection is mandated for such **pharmaceuticals and agricultural chemicals** which contain a **new chemical entity**. However it has not been laid out clearly as to the manner in which this data protection should be provided

1.4 According to industry sources the development and marketing of a new drug or a new agro-chemical entails extensive chemical, pharmacological, toxicological and clinical research and testing involves a huge cost and considerable time. The data generated, while proprietary to the originator, must be submitted to the regulatory authorities of countries to seek marketing approval of the new product. The proprietary nature of the data generated for obtaining marketing approval has been widely recognized. Article 39.3 of TRIPS pertains to such data and its protection.

1.5 Data Protection is meant to provide a fillip to research and development necessary to bring a product to market. Article 39.3 contains a few general terms such as **new chemical entities**, **considerable effort** and **unfair competition**. These terms have been interpreted differently by different countries owing to the flexibility in Article 39.3 enabling them to adopt an approach best suited to their needs and circumstances. Several countries have introduced trade secret form of protection in compliance of Article 39.3. On the other hand most developed countries have adopted data exclusivity as the mode of protection complying with Article 39.3 obligation.

1.6 The term data protection is generally interpreted to provide one or both of the following two types of protections –

a) Trade Secret as a form of Protection –

Trade secret protection implies that confidentiality of registration data is protected against its unauthorized use or disclosure. Trade secret form of protection does not expire; instead it remains effective until the trade secret owner no longer

takes steps to prevent disclosure of the information. The Regulatory Authority is free to utilize information for the performance of its statutory functions under the relevant Act and can rely upon this information to grant marketing approval to subsequent applicants for similar products without disclosing the confidential information to them. This concept basically implies “non-disclosure” of the confidential data by the Regulatory Authority.

b) Data Exclusivity as a form of Protection:-

Under this type of protection the Regulatory Authority cannot rely on the data submitted by the Originator for approving the second and subsequent applications for the same product. This concept implies non-disclosure as well as non-reliance on the first applicant’s data by the Regulatory Authority at the time of granting marketing approval to the subsequent applicants. Such protection is for a specific time period.

1.7 The opinion in India on this issue has been widely divided. Several meetings of the Inter-Ministerial Committee were held but no consensus could be reached on the issue. Subsequently, meetings of Secretaries and other senior officers of the concerned departments were convened on 22nd May, 2006, 26th July, 2006 and 6th September, 2006 under the chairpersonship of Secretary, Chemicals and Petrochemicals to take a view on the matter. These were attended by Secretaries of Department of Industrial Policy and Promotion (Sh Ajay Dua), Department of Scientific and Industrial Research (Dr RA Mashelkar), Special Secretary, Department of Commerce (Sh GK Pillai), Principal Advisor, Planning Commission (Sh Arvind Virmani) and senior officers of Departments of Economic Affairs, Agriculture, Health, Biotechnology and AYUSH². The issue of providing data protection for traditional / herbal products as distinct from other pharmaceuticals was brought out by the Department of AYUSH in the meeting held on 6th September, 2006.

1.8 One view in these meetings was that Article 39.3 does not require any kind of fixed period data protection (data exclusivity). There is no express provision to this effect and therefore India is under no obligation to provide the same as it may be TRIPS-plus. Each country is free to adopt its own approach. Over the years Indian pharma industry has developed a strong capability as a producer of good quality low priced generic medicines and any exclusivity provisions may adversely affect the

² Department of Ayurveda, Yoga and Naturopathy ,Unani,Siddha and Homeopathy under the Ministry of Health and Family Welfare , Government of India

interests of domestic industry as also lead to increase in prices of medicines in the country. Concerns were also expressed about the critical need for anti-HIV/AIDS drugs to be available at low prices as HIV/AIDS has become a major health concern for the country.

1.9 The other view which was expressed in the meetings was that there is need to take steps to facilitate early entry of new drugs in the country. With increasing globalization of the Indian economy, introduction of new products /technology will depend on how Indian rules compare with those of other peer competitors. The Committee was informed that most of the developed countries as well as several countries in South-East Asia have data protection for fixed periods ranging from 5 years to 10 years in case of pharmaceuticals and longer periods in case of agro-chemicals. China has data protection for 6 years in the case of both pharmaceuticals and agro-chemicals. Absence of data protection in India may discourage introduction of new products not under patent protection in the country, particularly biotechnology products. Data Protection may also result in stepping up of R&D by Indian companies. Some of these companies are already working on new molecules which may be introduced in the market in the next few years. Such efforts need to be encouraged and data protection can play a critical role.

1.10 Data protection is required both for patented as well as for non-patented drugs and agricultural chemicals. In the case of patented products although the product is under patent protection but the huge data that gets generated during the development stage does not enjoy such protection. This data has to be submitted to the Regulator by the originator for the purpose of getting marketing approval. Without protection the test data may be put to unfair commercial use by the subsequent applicants. Many of the new non-patented drugs marketed in other countries have their generic equivalents in India. However, there are a large number of drugs which are mainly biotech drugs e.g. the monoclonal antibodies (MAB) which are clones of a single parent cell and which target sites in the body responsible for diseases – like cancer, tetanus and a host of other indications. It is difficult to make generics of such drugs. Although some of Indian companies have succeeded in doing so, yet there is lot more to be done in this area. In case data protection is provided, such categories of drugs may become available early in India as the innovator companies would have greater confidence in entering the Indian market.

1.11 Another important issue of concern has been that of spurious drugs and chemicals . While spurious drugs have played with the health and lives of patients,

spurious pesticides have contributed to crop failure and financial bankruptcy of farmers. Data Protection may be helpful in checking this menace and only those companies which have the resources to produce good quality products should be allowed to market them during the period of protection.

1.13 After detailed deliberations it was noticed that there is enough flexibility in the provisions of the TRIPS Agreement for a country to determine the appropriate means of protecting test data. In terms of paragraph 4 of Doha Declaration, the provisions are to be *“interpreted and implemented in a manner supportive of WTO Members’ right to protect public health and, in particular, to promote access to medicines for all”*.

1.12 Hence, the policy decision needs to be taken keeping in view the national interest of the country by making use of the flexibilities in the TRIPS Agreement, in particular the need to ensure rapid and timely response to public health needs by facilitating timely entry of generics and encouraging competition. The ethical issues of conducting repeated human trials when data on quality and efficacy already exists should also be kept in mind. At the same time, the need to adequately promote innovation and R&D in pharmaceuticals and agro-chemicals by utilizing the rich human capital and the infrastructure available in the country should also be considered. This will help build India’s strength in these areas on a long term sustainable basis.

Chapter - 2

2.0 Some Important Issues pertaining to Data protection

2.1 Significance of Obligations under TRIPs Article 39.3

The TRIPS Agreement, which was negotiated as part of the Uruguay Round of trade negotiations under the GATT, the predecessor organization to the World Trade Organization (WTO), is the first international intellectual property agreement to include obligations for the protection of trade secrets, especially the proprietary data submitted by innovators to Governments.

A growing commercial significance of data protection is being realized for products that are not under patent protection due either to the new chemical entities not meeting the novelty test for a patent or there may be new uses of products, whose patents have expired.

Article 39.3 contains two obligations - protection against disclosure and protection against unfair commercial use.

2.2 Data entitled for protection:

Article 39(3) provides for protection to undisclosed test and other data, generation of which has entailed considerable effort not only in economic terms but also from a technical and scientific point of view.

In order to demonstrate that a drug is safe and effective for its intended therapeutic use, the originator of the drug has to conduct extensive testing on animals and humans in preclinical and clinical trials apart from toxicology and other scientific studies. These trials and studies yield significant test data and information which is proprietary in nature. This is contained in the registration dossier submitted to the regulatory authority for obtaining marketing approval for the drug. An almost similar situation prevails for agrochemical products. The generation of this proprietary registration data is at a considerable cost in terms of time and money to the innovator. In many cases patent protection is available to such products. However, in case of compounds, which for whatever reasons are not patent protected, data generated at great expense and effort and submitted to a regulatory

authority to obtain marketing approval for that product also requires some protection. There would be no obligation on the part of the Regulator to protect data which is in the public domain or which does not satisfy the above criteria.

2.3 Unfair Commercial Use:

The term 'unfair commercial use' has not been defined under The TRIPS Agreement and has therefore been interpreted differently by various countries. There has been intense debate on whether it implies data exclusivity or not. Industry in India is also divided over the issue. Some are of the view that reliance placed by Regulatory Authorities on the data submitted by the first applicant for granting marketing approval to the subsequent applicants comes in the category of 'unfair commercial use' under Article 39(3). They, therefore, argue that a fixed period of data protection should be provided, during which the Regulator cannot place reliance on the data of the first applicant while granting approval to the subsequent applicants for the competing generic versions of the innovator's products. The implication is that a subsequent applicant will be required to generate the required data at his level for seeking marketing approval of the generic drugs.

According to the other view held by several developing countries, Article 39.3 does not require exclusive rights to be granted but obliges protection in the framework of unfair competition rules. Under this interpretation, a second or subsequent applicant should be prevented from using the results of the tests undertaken by the first applicant if the respective data had been acquired through dishonest commercial practices. However, a government authority would not be prevented from relying on the data presented by the first applicant to assess submissions by the second and subsequent applicants for similar products. In many countries, including India, the Regulators are able to accord marketing approval for a new drug/ agrochemical based on bio-equivalence and bio-availability data matching the innovators' drug/agrochemical. In such cases, the innovator's/ first applicant's data is not called for by the Regulator and so the question of reliance does not apparently take place though reliance on it is implicit.

2.4 Meaning of 'New Chemical Entity' (NCE):

Article 39(3) grants protection to test and other data relating to pharmaceutical and agricultural chemical products which utilize 'new chemical entities'. The term "New Chemical Entity" has not been specifically defined in the TRIPS Agreement.

Different countries have, therefore, sought to interpret this term differently keeping in view their national interests.

There has been a debate as to whether the term “New Chemical Entity” should be evaluated in terms of the novelty requirement under the Patent law. It may be mentioned here that examination of novelty in patents is the process of discovering the uniqueness of the product over others in its field. As against this, the procedure adopted for market approval of drugs and agro-chemicals focuses on testing for efficacy and safety of the product. The objective is to ensure that new products satisfy health and safety requirements and not to ascertain whether the product is novel or not.

Article 39.3 does not clarify whether newness should be absolute (universal)³ or relative (local) i.e. whether newness would be for the first application in the world or in the member country where it has been filed.

Some countries like USA have adopted relative novelty standard and new⁴ chemical entity has been defined as – ‘a drug that contains no active moiety that has been approved by the Food and Drug Administration (FDA) in any other application’

In other words, although a drug containing an active moiety may not have⁵ been approved by the FDA and is, therefore, treated as a ‘new chemical entity’, it is possible that such active moiety is already known or described in scientific or technical literature -and is not therefore ‘universally’ novel.

The basic issue for consideration is whether the scope of ‘NCE’ is limited to drugs and agro-chemicals comprising first indications or whether it includes those comprising second indications also.

There is a view that even second indications require significant data for the marketing of drugs with modification in use, dosage or combination as the regulatory Authorities insist on data regarding safety and efficacy. It is argued that the generation of this data involves considerable effort and expense and, therefore, it should also be accorded the protection available under Article 39(3) irrespective of the fact whether the drug includes any new molecule or not. It is also argued that it would be unfair to limit the protection to the data of drugs with entirely new

³ Shammad Basheer , Associate , Oxford Intellectual Property Research Centre, University of Oxford

⁴ - do -

⁵ - do -

molecules as most of these would be under patent and are anyway protected under patent laws.

Since TRIPS lays down only minimum standards, each country is free to define a new chemical entity

Keeping in mind the requirements of Article 39(3) and its interpretations, a definition for an NCE needs to be prescribed.

2.5 Data Protection and Patents - distinct forms of protection

Data protection and patents are the two most critical and relevant intellectual property rights for the pharmaceuticals and agro-chemicals industry. These are distinct forms of protection – protection of one right is neither dependent on the other nor linked to the other. The distinctive character of each of these intellectual property rights is reflected in the structure of the TRIPS Agreement, which assigned each right to a separate section in Part II of the Agreement.

Data protection is **different from patent rights** that may exist for a particular product. Patent provides exclusive rights over a product. It gives the right holder the right to exclude others from making, using, selling, offering for sale, or importing the patented product. It is granted on patent application filed many years before the product comes up for marketing approval. It is only available to inventions which are novel, involve an inventive step and have industrial application.

Data protection on the other hand comes into picture at the time of grant of marketing approval to a new product which may be patented or non-patented. Since companies are under obligation to provide test data to Governments for getting market approval, such data needs some protection against unfair commercial use and from disclosure. This protection can be accorded by Governments to the proprietary test data and not to the product. The generic companies can generate their own tests and seek marketing approval based on that for a similar product. Therefore, there is no obligation to limit data protection to patented products only. **The issue of data protection becomes especially relevant for off-patent products as well as for products such as biologicals that are often difficult to patent.**

There have been different views as to whether data protection under Article 39.3 of TRIPS is to be extended to only patented products or to all new products whether patented or not.

A reading of Article 39.3 and the view held by several experts makes it clear that Data protection for a new product is independent of the fact whether such a product is patented or not

2.6 Reliance on Data submitted to a Foreign Regulatory Authority⁶

Article 39.3 obliges members to protect only that data which is⁴ submitted to their regulatory authorities and not to foreign regulatory authorities. This becomes evident from a reading of the Article 39.3 which begins by stating 'Members, when requiring...'

According to Prof Carlos Maria Correa, University of Buenos Aires, Argentina and a renowned authority on IPRs -

'Given the territoriality of the intellectual property system – a feature that the TRIPS Agreement has not altered – the obligation to protect test data only arises in the Member countries where national regulations require the submission of such data. If a Member country opts not to require those data, Article 39.3 will not be apply'.

Article 39.3 should apply to that data which is submitted to the National Regulatory Authority of a country. It would not apply in cases where submission of data has been waived by the Authority on the basis of an earlier marketing approval granted to the same drug or its equivalent in another country. In other words, the concerned National Regulator relies on the foreign approval (which in turn is based on submission of regulatory data by the Originator in that specific foreign jurisdiction) to grant an approval to market within its national boundaries. The rationale behind this is that approval of the same drug in another country is sufficient evidence of the safety and efficacy of the drug concerned and tests need not be duplicated again in the new country where such approval is sought. However, since the TRIPS Agreement establishes only the minimum standards for protection, member states may or may not provide for data protection in respect of data submitted abroad.

⁶ Presentation of Regulatory Data under Article 39.3 of TRIPS : The Indian Context - Shamnad Basheer

In India, under Rule 122B of the Drugs and Cosmetics Rules, 1945 (as amended) the manufacturer of a new drug while applying for approval to the licensing authority is required to submit data as mentioned in Appendix I to Schedule 'Y' of the Drugs and Cosmetics Rules, 1945 including results of the clinical trials carried out in the country in accordance with the guidelines specified in Schedule 'Y'. However, the Drug Regulator may in public interest waive the requirement of submitting results of clinical trials and grant permission on the basis of data available from other countries. Similarly submission of requirements of other test data like animal toxicology, reproduction studies, teratogenic studies etc may be modified or relaxed in case of a new drug approved and marketed for several years in other countries and there is adequate published evidence regarding the safety of the drug.

In the case of agricultural chemicals the Originator under section 9(3) of the Insecticides Act, 1968, the first registrant is required to submit all kinds of test data pertaining to safety and efficacy of the product, both done in the Originator's country and specific test data generated in India. However, the subsequent registrants of 'me too' category of products under section 9(4) of the Act are not required to submit the test data required of the first registrant.

Chapter – 3

3.0 Whether or not the Indian Legal Framework is adequate for purposes of data protection in accordance with TRIPS:

In India, there is no separate legislation to protect the unauthorized use /disclosure of confidential information. The existing legal mechanisms are the common law, principles of equity and the law of breach of confidence (also known as law of trade secrets) developed through case law. Protection is also provided through the provisions of Law of Torts and the Indian Contract Act, 1872 where remedies available being compensation and injunction. Section 5 of the Official Secrets Act provides that unauthorized disclosure of official secrets is a punishable offence. This provision is also applicable to government employees.

The Drugs and Cosmetics Act, 1940 regulates manufacture and market approval of drugs while The Insecticides Act, 1968 deals with agricultural chemicals (insecticides, fungicides and weedicides). Both these Acts have the obligation to insist on the submission of valuable test data signifying safety and efficacy for granting marketing approval for new drugs and agricultural chemicals.

3.1 Pharmaceuticals

The provisions dealing with undisclosed information for pharmaceuticals products are contained in the Drugs and Cosmetics Rules, 1945. Rule 53 provides that an inspector of Drug Regulator shall not without the sanction in writing of his official superiors, disclose to any person any information acquired by him in the course of his official duties.

In part X-A of the Drugs and Cosmetics Rules, 1945 dealing with the import or manufacture of New Drug for clinical trials or marketing, a broad definition for New Drug has been used, which includes new chemical entities, new combinations, dosages and new indications. Rule 122E defines 'New Drug', as follows:

“(a) A drug as defined in the Act, including bulk drug substance which has not been used in the country to any significant extent under the conditions prescribed,

recommended or suggested in the labeling thereof and has not been recognized as effective and safe by licensing authority mentioned under rule 21 for the proposed claims. Provided that the limited use, if any, has been with the permission of the licensing authority.

(b) A drug already approved by the Licensing Authority mentioned in Rule 21 for certain claims, which is now proposed to be marketed with modified or new claims, namely, indications, dosage, dosage form (including sustained release dosage form) and route of administration.

(c) A fixed dose combination of two or more drugs, individually approved earlier for certain claims, which are now proposed to be combined for the first time in a fixed ratio, or if the ratio of ingredients in an already marketed combination is proposed to be changed, with certain claims, viz, indications, dosage, dosage form (including sustained release dosage form) and route of administration.

Explanation – for the purpose of this rule:

(i) All vaccines shall be new drugs unless certified otherwise by the Licensing Authority under Rule 21;

(ii) A new drug shall continue to be considered as new drug for a period of four years from the date of its first approval or its inclusion in the Indian Pharmacopoeia, whichever is earlier.

As laid down in Rule 122A, 122B and 122D, various test data are required to be submitted to the Drug Regulator to obtain its approval to manufacture a New Drug or to import it. But these Rules also provide discretion to the Drug Regulator to waive the requirement to submit the results of local clinical trials if the drug is of such a nature that in public interest he decides to grant such approval on the basis of data available from other countries. Further the requirement for submission of test data related to animal toxicology and related studies etc also be modified or relaxed in case of new drugs approved and marketed for several years in other countries if the Drug Regulator is satisfied that there is adequate published evidence regarding the safety of the drug. However, the term several years has not been defined, thus leaving considerable discretion with the Drug Regulator. In such cases, where a drug is already being marketed in any part of the world, only data of confirmatory clinical trials is required to be given for obtaining the approval to market it in India for

the first time. The subsequent marketing approvals can be given on the basis of only bioequivalence and bioavailability studies. Conducting confirmatory clinical trials or bio-equivalence/bio-availability studies is a far simpler exercise requiring much less time, effort and money than conducting the full set of clinical trials.

On January 20, 2005, Ministry of Health and Family Welfare, Government of India amended Schedule 'Y' of the Drugs and Cosmetics Rules, 2005 . This Schedule deals with the requirements and guidelines for permission to import and/or manufacture New Drugs for sale or to undertake clinical trials. Sub-para (3) of para-1 in Schedule -Y dealing with applications for permission to import or manufacture New Drugs for sale in India clearly lays down that for drugs indicated in life threatening/serious diseases of special relevance to the Indian health scenario, the toxicological and clinical data requirements may be abbreviated, deferred or omitted, as may be deemed appropriate by the Drug Regulator.

The above factual position needs to be viewed in the context of the rationale for having in place the TRIPS Agreement and two subsequent Agreements, viz Doha Declaration on the TRIPS Agreement and Public Health and the Agreement on implementation of paragraph 6 of the Doha Declaration on TRIPS and Public Health

Para 4 of the Doha Declaration states that: "We agree that the TRIPS Agreement does not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be supportive of WTO Members' right to protect public health and , in particular , to promote access to medicines for all."

In pursuance of the Doha Declaration, the General Council of WTO, vide its decision of August 30, 2003, arrived at the solution to the problem faced by a large number of the WTO Members, referred to above. An amendment to the TRIPS Agreement that incorporates the essence of this decision was adopted on December 6, 2005. Through this decision, the obligation of an exporting Member under Article 31(f) of the TRIPS Agreement has been waived with respect to the grant by it of a compulsory licence to the extent necessary for the purposes of production of a pharmaceutical product and its export to an eligible importing Member, i.e. to a least developed country with insufficient manufacturing capacity.

3.2 Traditional Medicines⁷

Since time immemorial, India has possessed a rich traditional knowledge of ways and means practiced to treat diseases afflicting its people. This knowledge has generally been passed down by word of mouth from generation to generation. Some of them have been described in ancient classical and other literature, often inaccessible to the common man. Ayurveda, Siddha and Unani medical systems are collectively termed as “Indian Medicine” in the Indian Medicine Central Council Act, 1970.

Chapter IV-A of the Drugs and Cosmetics Act, 1940 contains provisions relating to Ayurvedic, Siddha and Unani drugs.

3.2.1 Types of products

About 95% of the Ayurveda products are herbal, may be of single ingredient or multi-ingredient. Both single-ingredient and multi-ingredient formulations are manufactured by the licensed manufacturers and used by the practitioners. Multi-ingredient formulations have broad range of action and are based on the principle of synergy of herbal constituents and suitability for desired therapeutic action. Ingredients of animal origin and minerals are also used in Ayurveda products, but they are fewer in number. Again, such products may be made up of one ingredient or more than one ingredient. Processing with herbal juices or extracts and combining herbal ingredients are by and large done in these products.

Only natural substances in wholesome form are used in the preparation of Ayurvedic products. As per definition of Ayurveda, products given in classical texts, substances other than natural products (plant products, animal products and minerals) were not recommended until two years back when permission for use of selective excipients, preservatives, anti-oxidants etc. was given to Ayurveda manufacturers.

3.2.2 Classification as medicinal products: As per the Drugs & Cosmetics Act, 1940 Ayurveda, Siddha or Unani drug include all medicines intended for internal or external use for or in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals and manufactured exclusively in accordance

⁷ Based on the information furnished by Department of Ayurveda, Yoga & Naturopathy, Unani, Siddha and Homeopathy (AYUSH).

with the formulae described in, the authoritative books of Ayurvedic, Sidhha and Unani Tibb systems of medicine, specified in the First Schedule.

3.2.3 Use of the different products/differences:

Therapeutic properties of formulations and guiding principles for their use are mentioned in the classical texts. Based on this information, individual professional expertise & skill and evidence generated out of scientific validation of the efficacy and therapeutic indications, practitioners prescribe Ayurvedic medicines along with precautions for diet, physical activity, behaviour etc. The patient's body-mind nature is also taken into consideration in planning the treatment regimen. Products made of simple, safe and commonly used medicinal plants and having nutritional properties are used as health foods or food supplements and as OTC products for management of common ailments. R&D-based medicines with specific indications are prescribed and used accordingly.

3.2.4 Statistical data⁸

Classical Ayurvedic products are like generic medicines. More than 85,000 formulations are identified as described in the 54 classical texts of Ayurveda enlisted in the Drugs & Cosmetics Act. However, the number of most commonly manufactured and marketed products is in the range of 800-1000. Patent & Proprietary medicines developed on the basis of personal experience and R&D are many more and their number may go into hundreds of thousands.

3.2.5 Availability of bibliography to demonstrate long-standing use-safety/efficacy:

Bibliography to demonstrate long-standing use of Ayurvedic formulations is available in two forms. Firstly, the use of classical formulations dating back from 3000 years onwards is available in compendia like *Charak Samhita*, *Sushrut Samhita*, *Astang Sangrah* etc. These classical formulations, wherever necessary, bear the precautions for patients as well as for practitioners and have been in continuous use in the country. That is why 54 classical texts containing such formulations are approved in the Drugs & Cosmetics Act for grant of license for their commercial manufacturing without any change in the composition and

⁸ 7997 Ayurveda drug-manufacturing units exist in the country. About 60% of them comply with GMP as per Schedule 'T' of the Drugs & Cosmetics Act.

proportions of ingredients. Secondly, there are companies, manufacturing about 500 different Ayurvedic medicines for the last 75-100 years and health hazards from their consumption are not reported.

Regarding proprietary & patent formulations, only such formulations are designated as Ayurvedic and are given manufacturing license, which have ingredients mentioned in the classical texts approved as per the Drugs & Cosmetics Act.

3.2.6 Evaluation and registration process:

- (i)** Central Government in the Ministry of Health & Family Welfare, Department of AYUSH is responsible to oversee regulation of Ayurveda, Siddha, Unani and Homeopathy medicines. Drugs & Cosmetics Act and Rules there under the Central Government is empowered for making regulatory provisions and amendments and to issue notifications. Technical and implementation / enforcement related to evaluation of medicines is done as under-
 - a)** Ayurveda, Siddha, Unani Drugs Technical Advisory Board (ASUDTAB) constituted under the provisions of Drugs & Cosmetics Act is an Expert Body chaired by Director General of Health Services to guide the Government on Drug related issues.
 - b)** Ayurveda, Siddha, Unani Drugs Consultative Committee (ASUDCC) comprising State Licensing Authorities and chaired by Drug Controller General is responsible to advise the Government on the implementation / enforcement issues of Drugs & Cosmetics Act.
 - c)** State Licensing Authorities are authorized to collect drug samples from the manufacturing premises as well as from the market for testing of their quality, purity and strength at Government approved Drug Testing Laboratories. Necessary legal action as per the provisions of Drugs & Cosmetics Act is liable to be taken against the defaulters. Standards of Identity, purity and strength of individual plant drugs and of compound formulations are given in the Ayurvedic Pharmacopoeia and Formulary respectively. Penal action against the defaulting drug manufacturers is provided in the Act for products found deviated from these standards and found as misbranded, spurious, adulterated or mislabeled.

- d) Central Pharmacopoeia Laboratories are the appellate laboratories for drug testing. Statutory samples of drugs referred from Central/State Government are tested in these laboratories and their testing reports form the basis of decision in legal matters.
- e) In spite of the many legal provisions for ensuring quality of marketed products, the onus still lies on the manufacturer, if product at any stage and in any way is found to be unsafe and is hazardous for public health. Legal action is provided for such cases.

(ii) Registration process.

Licensing of Ayurveda manufacturing units and products to be manufactured in these units is done by the State Drug Controller / State Licensing Authorities. In some States where Licensing Authorities are common for modern medicines and Ayurvedic medicines, Ayurveda experts are kept involved in the approval process. For seeking approval textual references of the formulation and the ingredients are required along with the rationale for the given combination in case of proprietary medicines.

3.3 Agricultural Chemicals

Agricultural chemicals consist of various chemicals like fertilizers, plant growth substances, soil amendment chemicals, insecticides / pesticides etc.

The Insecticides Act, 1968 was passed to regulate the import, manufacture, sale, transport, distribution and use of insecticides⁹ with a view to prevent risk to human beings or animals. Section 9(1) of the Act, mandates that any person desirous of importing or manufacturing any insecticide should obtain a Certificate of Registration from the Registration Committee constituted under the Act.

Import or manufacture of a new insecticide is registered under section 9(3). Any subsequent applicant for registration of the same insecticide is registered under Section 9(4) of the Act. This is commonly known as the 'me too' category. Such

⁹ Insecticide includes pesticides, fungicides and weedicides as specified in the Schedule of the Insecticides Act, 1968.

applicants need not submit data proving the efficacy and safety of the insecticide. They submit only the chemical composition and labels and leaflets which were approved for the original registrant

The Act also provides for provisional registration to insecticides, which are introduced for the first time in India. The validity of such registration is only for two years. Provisional registration is granted to enable the applicant to generate data for obtaining the original registration.

Following types of Registration Certificates are issued under the Act –

- a) Technical Indigenous Manufacture (TIM) - Manufacture of technical insecticides in India.
- b) Formulation Indigenous Manufacture (FIM)-Manufacture of Formulation (Final products for application on crops) from Technical manufactured in India or from imported Technical.
- c) Technical Import (TI)-Import of Technical Insecticide for manufacture of Formulated Insecticide.
- d) Formulation Import (FI)-Import of Formulated Insecticide for direct marketing.

After import of Technical insecticide, information is to be given to Registration Committee about location and Research Institute where scientific data on chemistry, bio- efficacy, toxicology & packaging of that insecticide will be generated for Registration of that Insecticide in India.

After intimation to Registration Committee, data on different parameters as mentioned above will be generated from different locations Research Institutes¹⁰. This is accompanied by full foreign published data support which is submitted to Registration Committee in India.

The Insecticides Act does not provide for any kind of protection to the data submitted for registration. Though Rule 29 creates an obligation on Insecticides Inspector to maintain confidentiality of information acquired by him in the performance of his office duties, this does not extend to the Registration Committee. Section 9(4) clearly empowers the Registration Committee to allow subsequent registration based on data submitted for original registration.

¹⁰ As per industry sources duration of data generation is about three years and approximate cost of data generation is Rs.30-35 lacs for each applicant.

For registration of insecticides about 40 different tests in chemistry, bioefficacy and residues and toxicity are required to be done. Some of these tests pertaining to bioefficacy, toxicity and chemistry are required to be done in different agro-climatic conditions in India. For rest of the tests data support from tests undertaken as per the OECD guidelines abroad are accepted in India.

It has been noticed that there are about 200 insecticides¹¹ registered in India sofar. Another 30 products are in the process of being registered. As compared to this the number of insecticides registered in some other countries is considerably higher e.g. 750 in USA, 550 in China, 600 in Europe, 480 in Pakistan, 450 in Vietnam, 450 in UK, 300 in Thailand.

¹¹ Based on information supplied by Hindustan Insecticides Limited (a Govt. of India Undertaking).

Chapter – 4

4.0 Current State of Data Protection across different countries:

There is no uniformity on the kind of data protection being provided by various countries around the world. It widely differs across the countries in the following ways-

- a) Data Exclusivity (fixed period data protection) is provided by many developed and other countries for different periods to both pharmaceuticals and agro-chemicals – eg. USA (5 years for pharmaceuticals and additional 3 years for new indications of existing drugs, 10 years for agro-chemicals), European Union (10 years for both and 1 extra year for new indication in case of drugs), Canada (8 years), Japan (6 years for both) China (6 years for both)
- b) Some countries like Brazil provide data exclusivity for agro-chemicals only and not for pharmaceuticals
- c) Several developing countries, including India, do not provide data exclusivity or fixed period data protection to pharmaceuticals and agro-chemicals

It is, thus, clear that different countries have made use of the flexibilities in the provisions of TRIPS suiting their needs and interests .India can also adopt a model which best suits its interests

It may be mentioned here that in the case of the Patent law also India has made adequate use of the flexibilities in the TRIPS Agreement and provided safeguards necessary for its public health needs.

Chapter-5

5.0 Registration Data requirements for Agro-chemicals different from that of Pharmaceuticals

5.01 The general protection over test data under Article 39.3 applies to both pharmaceutical and agrochemical sectors, yet the data requirements for getting marketing approval are quite different for the two. Accepting the difference, the great majority of legislations across different countries regulate the protection of safety and efficacy data differently for both as to the term and form of protection of safety and efficacy studies

This differential treatment is mainly due to the following reasons:

- (a) Unlike pharmaceuticals, efficacy tests for agro-chemicals must be repeated in every country, even in several regions in a country due to differences in crops, pests, agronomical practices, climate conditions and terrains.
- (b) Because of the toxic nature of the substances involved the crop protection industry must face a responsibility for environmental impact to which the pharmaceutical industry is not exposed.
- (c) Further in case of agricultural chemicals, the process of data generation continues even after the product registration has been done due to the requirements of periodic review, data call in by the authorities, adaptation to the advanced standards of science and technical knowledge, product stewardship etc. Failure to meet these requirements may lead to revocation of product registration.
- (d) The costs involved in conducting the above registration related studies for agricultural chemicals are huge. Product registration is only the first part of the cost. The originator incurs substantial subsequent costs on extension and development work involving door to door contact with the farmers in villages to ensure better use to obtain the optimum results, without compromising safety.

- (e) While in the case of pharmaceuticals one in every 10,000 molecules investigated is approved by the FDA for marketing, in the case agro-chemicals only one of 20,000 molecules makes it from the laboratory to the fields.
- (f) Because of its chemical nature and the wide range of organisms potentially affected by their use, agro-chemicals products have to undergo more than 40 safety tests

5.2 Position in India

- (a) In India, before a new crop protection product is introduced the applicant is required to generate substantial data on bio-efficacy, toxicology, process of manufacture, effect on environment, safety of spray operators, compatibility with containers as also transportation and stability. As per industry sources these studies are spread over 3 to 4 years and have to be conducted to meet the requirements of the Indian registration system. In the case of pharmaceutical products elaborate data on toxicology studies and clinical trials on a large number of healthy volunteers and patients is not insisted upon by the Drug Regulator and marketing approval obtained by the innovator in another country is considered sufficient for grant of marketing approval in India, subject to confirmatory trials on a small number of patients and bioequivalence with the innovator's drug.
- (b) Once the original registration is obtained by the originator/ first applicant u/s 9(3) of the Insecticides Act(1968), a large number of 'me too' registrations are obtained immediately, u/s 9(4) of the Act – virtually without any test data
- (c) All the 'me too' registrants may not have complete knowledge of the compound they produce through reverse engineering. Consequently there is no transfer of knowledge/technology to the users of new but 'me too' products, sometimes leading to indiscriminate and wrong use of such products. This may have adverse consequences i.e. development of resistance/ uneconomic returns to the farmer, adverse effects on health and the environment.

- (d) Innovators are reluctant to bring the latest discoveries to India. The 'me-too' registrant is at an unfair advantage since he has not incurred the huge costs either on trials in different agro-climatic zones in India or on the 3-4 years stewardship or supervised application. This deprives the country and the farmer's access to insecticides which are more effective, environment friendly and have lower dosage
- (e) It is noticed that there are only about 200 insecticides registered in India so far. Another 30 products are in the process of being registered. As compared to this the number of insecticides registered in some other countries is considerably higher e.g. 750 in USA, 550 in China, 600 in Europe, 480 in Pakistan, 450 in Vietnam, 450 in UK, 300 in Thailand.
- (f) There is an increasing tendency on the part of multinational companies to import pesticide formulations from abroad. As per the registration procedure formulation imports can be done only under section 9(3) of the Insecticides Act, 1968 and 'me too' under section 9(4) is not permitted. This prevents manufacturing of such insecticides in the country and no 'me too' can come at any stage
- (g) In the case of pharmaceuticals, information regarding the correct drug and its dosage form for a particular disease is conveyed to the consumer through the doctors. In agro-chemicals this role is discharged by the companies after introducing the chemical in the market through extension services and stewardship for 3 to 4 years. 'Me-too' registrants do not undertake this supervision as it involves huge cost and often because of lack of adequate knowledge of the compound they have copied through reverse engineering.
- (h) This deficiency on the part of 'me-too' registrants and poor quality of the products has in some cases resulted in application of the wrong agro-chemicals or its excessive use causing financial loss to the farmers, and sometimes laying waste precious agricultural land.

Looking to the wide differences in the data requirements of the pharma industry and the agro-chemicals sector for registration different approaches of data protection are needed for these two sectors.

5.3 Different Approaches by countries for agro-chemicals and pharmaceuticals-

In several countries, there is no uniform policy in the matter of data protection for these two sectors. Prof. Carlos Maria Correa of University of Buenos Aires, Argentina and a renowned authority on IPRs has clearly brought out the fact that “Countries have considerable discretion to define unfair in the context of their own national laws and culture. TRIPS Agreement is not a uniform law – it only establishes broad parameters for national rules.’

Generally the protection allowed for agro-chemicals is higher than that for pharmaceuticals. In USA there is 10 years data exclusivity for new agro-chemicals from the date of registration + 15 years additional protection on the basis of compensability, as against 5 years data protection for new pharmaceuticals. Similarly in Europe it is 10 years + 5 years for additional data, in UK it is 8 years, in Japan it is permanent, in Canada it is 10 years, in France too it is 10 years and so on and so forth.

Brazil too has adopted a different policy for the two sectors. While data exclusivity is not allowed for pharmaceuticals, it is allowed for 10 years for the agro-chemicals with 5 years for additional data required by the regulatory authority to sustain / maintain registration of a given agrochemical product.

Chapter –6

6.0 Possible Alternatives

6.01 In the light of flexibilities in the provisions of TRIPS Agreement, the policies adopted by various countries and the views of experts towards protection of test data under Article 39.3 of TRIPS, different alternatives were discussed in the Inter-Ministerial Committee and also separately with various stakeholders. Various alternatives in the context of India were discussed. These are as under: -

6.1. Data Protection for Agro-Chemicals:

6.1.1 Fixed period Data Protection for three / five years (with non- reliance by Regulator on the test data of the Originator while granting marketing approval for the same product to the second and subsequent applicants)

6.1.2 The special need for data protection in case of agro-chemicals has been discussed in Chapter-5. In order to attract new generation pesticides in India, which are low volume, high value products and require very low dosages, it was generally felt that there is need to provide a fixed period data protection which may be for three or five years. During this period the Regulator would not be able to rely on the test data of the first registrant for the purpose of approving second and subsequent applicants of 'me too, category of the same products. The effect of this would be that for a period of three/five years, the 'me too' would not be able to enter the market without the express consent of the originator. The justification for this type of protection has been extensively discussed in Chapter-5.

6.1.3 While there has been a broad consensus among various industry associations as regards data protection for a period of three years several experts feel that three years may be inadequate and it should be at least for five years to enable the long period of promotional work required for educating the farmers on the use of new chemicals. Fixed period Data Protection may provide some incentive to bring new pesticides into India which are environment friendly, safer and more effective. In case this approach is adopted it should be accompanied by adequate safeguards which may be essential in the interest of the country and the farmers.

6.1.4 Safeguards:-

(a) Proposed protection shall not be extended for sustaining registration, deregistration or data call in.

(b) In case of new chemicals which are patented in India, data protection shall not exceed the term of patent .

(c) All the provisions of data protection can be waived / relaxed by the Government in the following circumstances and 'me-too' registrations allowed–

- a) circumstance of national emergency
- b) extreme urgency
- c) public health crisis

(d) The Government can relax/waive the provisions of Data Protection:

- (i) if the protected product is not available to the public at a reasonably affordable price;
- (ii) in public interest;

Public interest may include the following grounds: -

- Protected Product not being made available in the territory of India,
- Reasonable requirements of the public with respect to the product not being satisfied.
- Exceptionally high prices of the products(e)

(e) The provisions of the data protection can be waived by the Government for its own use, for academic and research purpose. In these cases, Government and its institutions will be bound to observe non –disclosure of data and its protection against unfair commercial use.

(f) The Regulatory Authority for granting marketing approval to agro-chemical products shall be free to determine the requirement of data from the first applicant.

(g) Government will create a suitable mechanism to ensure that the prices of such agro chemicals continue to remain reasonable so that there is a wider coverage as far as the farmers are concerned.

(h) India should follow a system that will allow generic filing to be done during the Data Protection period. The Regulatory Authority could tentatively approve the product if it meets the regulatory requirements. The approval will automatically become final the day data protection expires.

(i) The protection for the above said data shall be available with effect from the date of registration in India.

6.1.5 Definition of New Chemical Entity (NCE) may be incorporated as follows:

“A chemical compound which contains an active ingredient or formulation of such an ingredient that has not been previously approved in India irrespective of its registration and use in any other country.”

Proviso:- The data protection will be limited to New Chemical entities (NCE), as required under article 39.3 of the TRIPS agreement.

6.1.6 Likely Repercussions:-

(A) Positive impact:-

a) This will facilitate arrival of newer and safer agro-chemicals for the benefit of Indian farmers, improving the yield and quality of their produce which would have a better market globally.

b) There is often no transfer of knowledge by ‘me-too’ registrants about the chemicals to the farmers resulting in wrong or overuse of ‘me too’ chemicals with adverse consequences like damage to crops, uneconomic returns, development of resistance etc.

c) Use of new crop protection products prevents adverse effects on the environment that is germane to repeated use in higher volume of conventional products. This is because the new solutions are applied in low doses, are target specific and are fast degrading.

d) It will encourage R&D based companies abroad to bring new technologies for the benefit of farmers and also encourage domestic companies and R&D institutions to invest in R&D in agro-chemicals.

- e) International companies may shift their facilities to India making India a hub for data generation and a base for global registrations.
- f) Fixation of minimum residue levels (MRLs) for products already in use are a mandatory requirement due to commitment of the Government in Parliament and before the Supreme Court. Generation of residue data involves substantial effort in terms of time and money. Provision of data protection will induce the companies to come forward to undertake the necessary investment in data generation.
- g) It will enable the original applicant to recoup the huge investment in conducting safety and efficacy studies for the new agro-chemical product, which generally takes 3 to 4 years.

(B) Negative Repercussions

This approach may be perceived to delay the entry of 'me-too' registration, during the three/five years period of protection, immediately after the launch of a new pesticide in India. During the period of data protection they will be required to seek the consent of the pioneer company for launching the same product in India.

The above approach on agro-chemicals was favoured by representatives of the Department of Industrial Policy and Promotion, Department of Scientific, Industrial Research and Planning Commission. Industry associations, CCFI, PMAFI, Crop Life India have also informed that there is a consensus among them for granting a fixed period data protection for three years.

6.2 Data Protection for Pharmaceuticals

6.2.1 A study of the position in the Drugs and Cosmetics Rules, 1945 shows that as per first proviso to rule 122(B) (3) the requirement of submitting results of local clinical trials may not be necessary if the drug is of such a nature that the licensing authority may in public interest, decide to grant such permission based on the data available from other countries.

6.2.2 The second proviso to Rule 122(B)(3) provides that the requirements of certain data can be relaxed if the drug has been approved and marketed for several years' in other countries and there is adequate published evidence regarding the

safety of the drug. In other words the need to provide some data protection is evident in this proviso and relaxation in generation of elaborate data would be not be allowed if the drug has not been marketed in other countries for several years and safety and other data is not in the public domain. The applicant in India submits published data of innovator pertaining to pre-clinical and clinical stages along with data generated by the applicant in India regarding toxicity, chemical, pharmaceutical information including quality control data, manufacturing data confirmatory clinical tests based on which marketing approval is granted to him. The term 'several years' has not been defined in these rules

Two kinds of approaches/alternatives were discussed -

Alternative -1

6.2.3 Trade Secret form of Data Protection against unauthorized disclosure and use of proprietary test data (Drug Regulator to continue to place reliance on data of first applicant while approving second and subsequent applicants)

(i) This option is based on the interpretation that provision for data protection is required only against unauthorized disclosure/use of confidential test data and this is sufficient to cover cases of unfair commercial use. The relief in such cases can be sought from the courts. There is no requirement or need for providing fixed period data protection (data exclusivity) on the data submitted by the originator. This view also holds that reliance placed by Regulatory Authority in India on the data submitted by the originator in a foreign country for approving registration of same products in India does not tantamount to unfair commercial use .

(ii) 'New Chemical Entity' (NCE) in the context of Data Protection does not mean a novel entity in the patent sense. It has to be seen from the angle of marketing approval. According to experts like Prof Carlos Correa, a renowned expert in IPR, a chemical entity is deemed new, if there were no prior application for approval of the same drug or where the same drug was not previously known to commerce. It would, however, not apply to new indications, new dosage forms, new combinations, crystalline forms, isomers etc. of existing drugs since, there would be no new chemical entity involved. Keeping this interpretation in view the 'NCE' for Pharmaceuticals needs to be clearly defined.

(iii) Protection of data against unauthorized disclosure/ use shall only be limited to the new drugs which fall under the definition of a 'New Chemical Entity'.

(iv) Government shall ensure that the specified data submitted for the purpose of marketing approval of pharmaceutical products should not be disclosed to any third party. Regulatory Authority will be under legal obligation to protect the data submitted to them for approval of new drug.

(v) The existing Indian Legal Framework dealing with undisclosed information is in the form of Official Secrets Act(section 5), Drugs & Cosmetics Act 1940 (rule 53 of the Drugs and Cosmetics Rules,1945), Law of Torts, The Indian Contract Act, 1872, and Insecticides Act 1968. It is felt by some experts that the present provisions are not sufficient to ensure the desired compliance level to fulfil India's obligation under Article 39.3 of TRIPs. Necessary provisions should be introduced in the Drugs and Cosmetics Act/Rules in this regard.

6.2.4 Likely Repercussions

(A) Positive impact:-

a) It will allow greater competition to take place by not giving monopoly rights to the innovator drug companies on the non- patented new drugs. This will help keep a check on the prices of these drugs.

b) It will help in greater availability of generic drugs as the domestic companies will continue to make generics of the pioneer drugs (not under patent) since Drug Regulator would continue to rely on the data provided by the first applicant while approving the subsequent applicants for similar drugs.

(B) Negative impact:-

a) It may have some adverse impact on FDI in pharmaceuticals sector in India since the perception with most international corporates may be that India does not provide adequate IPR protection to new products

b) This may slow down the early launch of some of the new drugs in India for lack of adequate protection

c) This may affect India's image as a country where innovation is not fully encouraged /protected .This may affect our entry into certain important Conventions like Pharmaceuticals Inspection Convention/ Pharmaceuticals Inspection Cooperation Scheme (PIC/S), Mutual Recognition Agreement (MRA) regarding GMP with European Union and other developed countries.

d) It may lead to increasing bilateral Free Trade Agreements by USA and other countries which may affect our generic exports. These FTAs generally include IPR restrictive clauses like 5 to 6 years data exclusivity , rigid procedures for parallel importation and other TRIPS plus provisions. All these may have negative implications for generic exports from India.

Alternative - 2

6.2.5 Fixed-term Data Protection for five years (with non reliance by Drug Regulator on the test data of the originator while approving same drug of the second and subsequent applicants) along with safeguards

- (i) All the measures for non disclosure as in Alternative-1 to be adopted
- (ii) The protection should only be for a New Chemical Entity (NCE), i.e. an active ingredient (excluding any ester or salt of the active ingredient) which has not been previously approved in any other application, and not to every "new pharmaceutical product".
- (iii) The protection should apply with prospective effect for molecules that were discovered after 1st January, 1995.
- (iv) In case of a patented drug the period of protection should in no case go beyond the 20-year period of patent protection as otherwise it would lead to extending the period of market exclusivity for a patented drug beyond its patent period.
- (v) The period of protection should be counted from the date of the first marketing approval granted anywhere in the world so that the drug companies market the new drug in India at the earliest.

(vi) Sections from 84 to 92A (compulsory licence) and Section 107 (Bolar Exception) of the Patents Act, 1970 should override the provision for data protection. India should follow a system that will allow generic filing to be done during the data protection period. The Regulatory Authority could tentatively accord marketing approval to the generic products of the pioneer product which is under data protection, if they meet the regulatory requirements. The approval will come into force immediately after the data protection period expires. This will provide immediate market entry to the generics on the expiry of data protection period.

(vii) Government will have the right to waive all provisions pertaining to data protection in case of a public health emergency. In such a situation, Government may rely on the data for granting marketing approval to another applicant.

(viii) In cases where and Government feels that repeating clinical trials for a drug is not essential, Government may direct the Regulatory Authority to place reliance on the first applicant's data .

(ix) Government will have the right to create a suitable mechanism to ensure that the prices of new drugs are reasonable for fulfilling the affordability and accessibility criteria in the public interest.

(x) The Regulatory Authority for marketing of pharmaceutical products should be free to determine the requirement of data from the first applicant.

(xi) The provisions should not restrain manufacture for export to countries, which either do not have provision for data protection or where the term of protection has expired.

6.2.6 Repercussions of Alternative - 2

(A) Positive side-

i) This will ensure that the elaborate efficacy and safety data is made available to the Regulatory authority to avoid any harmful effects of the drug on the public in future

- ii) It will encourage Indian and other pharmaceutical companies to focus their efforts on development of new drugs in India to treat diseases prevalent in India
- iii) It will facilitate early entry of newer medicines into India for the benefit of Indian patients.
- iv) This will project India as a country which encourages innovation in pharmaceuticals/ agro-chemicals
- v) It may help India in getting membership of important Conventions like PIC/S and MRA on GMP with EU and other developed countries
- vi) It may help in attracting greater FDI into India in the drug manufacturing and research areas. (though this is challenged by some experts) .

(B) Negative side:

- i) It may be perceived as a temporary barrier for early entry of generics by the domestic pharmaceutical companies in making generics of the pioneer drugs under data protection.
- ii) Due to slow entry of some of the generics drugs into India the prices of the pioneer drugs under data protection may remain somewhat high during the period of protection (though there would a safeguard for keeping a check on prices of such medicines)

The negative effects can be countered by providing adequate safeguards and by keeping a check on the prices of the drugs.

**6.3 Data Exclusivity with Compensatory liability approach: –
(For both agro-chemicals and pharmaceuticals)**

The Inter-Ministerial Committee also discussed the possibility of providing compensatory liability model for data protection as is applicable in some other countries, most notably USA. Both the concerned Departments i.e Health and Agriculture were of the opinion that there would be several practical difficulties in

implementing such a model in India at this stage. It was therefore decided to drop this alternative for the present

6.4 Data protection for Traditional Indian Medicines -

6.4.1 Documentation of the existing knowledge available in public domain on various traditional systems of medicines is essential to safeguard the sovereignty of this traditional knowledge and to protect them from being misappropriated. An ambitious project called the Traditional Knowledge Digital Library (TKDL) has been undertaken by Government of India. In the first phase 36000 Ayurvedic formulations from 14 authentic Ayurvedic texts have been transcribed into digitized format in five international languages, which are English, German, French, Spanish and Japanese to ensure ease of retrieval of traditional knowledge related information by patent examiners globally.

6.4.2 A large number of traditional medicines systems like Ayurveda, Siddha and Unani systems are being practiced in India. There has been a demand from various quarters that traditional medicines should be viewed differently from the chemical pharmaceutical products for granting data protection.

6.4.3 As per WHO study, traditional medicines are popular with almost 70% of the Indian population. Since most of these medicines are already in the public domain, there is no patent protection for these under the Indian Patent Act. There is, however, a need to develop proprietary medicines based on the raw materials described in the classical texts by promoting greater research and development, improving their efficacy and to find new uses for these. Data protection can play an important role in this regard. It was discussed that a fixed period of data protection for five years with non-reliance by the Drug Regulator on the data submitted by the first applicant while approving second and subsequent applicants, should be appropriate.

6.4.4 In several respects herbal/ traditional drug products are different from other pharmaceuticals in terms of their origin and characteristics, they are developed differently, have different regulations and enjoy lesser patent protection. In addition most of these products are already marketed. It would, therefore, be appropriate that these products are considered as a separate category for providing data protection.

6.4.5 There is a growing need to promote greater research and development in the traditional medicines to improve their efficacy and to find new uses for the same. Due to the absence of patent protection providing fixed term data protection (with non-reliance by Drug Regulator) on the data of first registrant for granting marketing approval to subsequent registrants can be helpful in promoting greater research in this area.

Chapter-7

Recommendations

Various approaches towards data protection as mentioned in Chapter-6 were deliberated upon extensively with various stakeholders, experts and members of the Inter-Ministerial Committee.

Based on a broad consensus and in the context of the peculiarities of India following approach is recommended –

7.1 Need to Strengthen Legal Provisions on Data Protection -

Article 1.1 of TRIPS provides that –

“.....Members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice.”

The present legal provisions on data protection in India do not adequately meet the spirit of Article 39.3 of TRIPS even in terms of the minimum requirements. There is need to lay down explicit legal mechanism in the Drugs and Cosmetics Act, 1940 and The Insecticides Act, 1968 and the Rules framed under these Acts to ensure that undisclosed test data of the originator is not put to unfair commercial use by others. This would generate greater confidence in the industry and encourage R&D in India. There is, however, no need for a separate legislation on this subject.

7.2 Different Data Protection Measures to be adopted for Agrochemicals, Pharmaceuticals, and Traditional Medicines

Looking to the special features of each of these product categories i.e. Agrochemicals, Pharmaceuticals and Traditional Medicines, it would be justified to have a different approach for each of them. The definition of a ‘New Chemical Entity’ would also differ in case of the three categories

7.3 A Calibrated Approach to be adopted in case of Pharmaceuticals -

There is an established system of marketing approval and evaluation of test data generated for drugs in India. While there is need to improve the system and

make necessary legal changes and explicitly provide for the minimum requirements under Article 39.3 of TRIPS, any higher standards of data protection should be done after a careful study of its impact on the sector and public to avoid any adverse repercussions in the long run. India has adopted product patent regime with effect from 1st January, 2005, the impact of which is yet to be seen. Therefore, a somewhat cautious approach may be in the interest of the country. Any misgivings in the public mind about the need or the justification for the new system need to be addressed over a period of time. A calibrated approach with a transitional period, therefore, appears to be best suited for India. During the transitional period, the minimum requirements under Article 39.3 of TRIPS can be implemented. Also, this period can be utilized to educate the public and industry so as to allay their apprehensions on the issue. The capacity and the physical infrastructure available with the Regulatory Authority would need to be suitably strengthened and upgraded.

7.4 Recommended Approach for Data Protection -

7.4.1 Agro-chemicals -

The recommended approach for data protection has been considered with high priority to the interest of farmers. They increasingly require safer and more convenient pesticide formulations such as water based emulsions in water flowable suspensions, micro encapsulation, water dispersible granules which are relatively safer with reference to environment. They are also considered safer for the farmers as regards skin and eye disorders. There has been a consensus among various industry associations for a fixed period data protection of three years with non-reliance by the Regulator on the test data of the first registrant while granting marketing approval to the second and subsequent applicants. In view of the justification as enumerated in Chapter-5 and broad consensus among industry associations for three years time frame¹², it would be appropriate to provide data protection for a period of three years. The period of three years would enable the innovator companies to undertake necessary stewardship required for dissemination of information to the farmers in order to acquaint them with correct dosage and method of application of the agro-chemicals to get optimum results. Absence of such extension work by companies may result in improper use of agro-chemicals by un-informed farmers causing harm both to the applicators and to the crops as without

¹² Crop Life India, Crop Care Federation of India (CCFI) and Pesticides Manufacturers and Formulators Association of India (PMFAI).

extension work farmers may tend to use larger quantities of agro-chemicals, resulting in financial losses.

Therefore the following approach along with safeguards is recommended -

- i) A fixed term data protection for 'three years' from the date of Registration in India, with the Regulator not relying on the data submitted by the Originator while granting market approval for same products of second and subsequent applicants. Thus Regulator during the period of three years would not accord approval for the same product to 'me too' category of applicants.**
- ii) Data of the Originator must be kept secure and not be accessed by any unauthorized person, nor be accessible to such person. All technical and organizational safeguards as are possible must be implemented.**
- iii) If data is transferred to any authority or entity, it must follow the same data protection requirements as in (ii) above.**
- iv) Other relevant provisions out of the ones suggested for pharmaceuticals at page 45-46 may also be adopted.**

Safeguards:-

In consultation with the Department of Agriculture following safeguards are recommended -

- i) In the case of new pesticides which are patented in India, data protection shall not exceed the term of patent granted.
- ii) All the provisions of data protection can be waived / relaxed by the Government and 'me-too' registration allowed in the following circumstances –
 - a) in case of national emergency
 - b) in case of extreme urgency
 - c) in case of public health or environment related crisis

(iii) Government can also relax or waive the provisions of Data Protection in public interest and allow 'me too' registrations

Public interest may include the following grounds: -

- a) When the product granted data protection is not being made available in the territory of India within six months of its registration in India,
- b) Reasonable requirements of the public with respect to the product not being met,
- c) Product not available at reasonable prices. Whether price is reasonable or not may be decided by Government.

Note: The Originator would be required to launch the product within six months of its registration and inform the Regulator of the same along with evidence.

(iv) The provisions of data protection can be waived by the Government for its own use, for academic and research purposes. In these cases, Government and its institutions will be bound to observe non –disclosure of data and its protection against unfair commercial use.

(v) The Government may, if necessary, create a suitable mechanism of price negotiations to ensure that the price of such new agro chemicals continue to remain reasonable so that there is a wider coverage as far as the farmers are concerned.

(vi) India should follow a system that will allow generic filing to be done during the Data Protection period. The Regulatory Authority could tentatively grant marketing approval for the products of the second and subsequent applicants if they meet the regulatory requirements. The marketing approval will be held in abeyance and will automatically become operational on the day following the expiry of the data protection granted to the first applicant.

(vii) Definition of New Chemical Entity (NCE), in the case of agro-chemicals, is suggested as follows:

“An agrochemical product which contains an active ingredient or formulation of such an ingredient that has not been previously approved in India irrespective of whether the product is patentable or not”.

Explanation –I – Data protection shall be granted to only post-1995 molecules which have not yet been introduced in India.

Explanation – II - Even if the product has been previously approved in another country it will remain an NCE in India till the time of its first approval in India. The applicant would be required to conduct studies in India to test its safety and efficacy in local conditions before getting market approval .

Based on the above approach , the Ministry of Agriculture may carry out suitable amendments in the Insecticides Act 1968 and relevant rules.

7.4.2 Traditional Medicines

Following is the definition of traditional medicines given by WHO-
“Traditional medicine (TM) is the sum total of knowledge , skills and practices based on the theories , beliefs and experiences indigenous to different cultures , whether explicable or not , used in the maintenance of health as well as in prevention , diagnosis , improvement or treatment of physical and mental illnesses.”

As per the Drugs & Cosmetics Act, 1940 such medicines are defined as ‘Ayurveda, Sidhha or Unani drug which include all medicines intended for internal or external use for or in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals and manufactured exclusively in accordance with the formulae described in, the authoritative books of Ayurvedic, Sidhha and Unani Tibb systems of medicine, specified in the First Schedule’.

Two types of Ayurvedic medicines are legally defined. Classical medicines, which are basically all classical formulations mentioned in the approved ancient texts and Proprietary medicines, which are based on formulations evolved by the manufacturers with such ingredients as are mentioned in approved classical texts. 54 classical texts, Ayurvedic Pharmacopoeia and Ayurvedic Formulary are the approved documents.

Though traditional medicines are considered part of pharmaceuticals yet they differ significantly in so far as their origin, ingredients, manner of development, regulatory aspects etc are concerned. Therefore it was felt that looking to their different features and lack of patent protection in most cases these products should be placed in a separate category for the purposes of providing data protection.

Government is in the process of setting up an autonomous regulatory body called the Central Drug Authority which would also provide for registration of all Indian traditional medicines (Ayurveda, Unani and Siddha systems). A large number of scientists, entrepreneurs, SMEs, corporates are working on the development and standardization of traditional medicines. Providing data protection to these products would encourage the much needed data generation for their scientific validation.

7.4.2.1 Features of Data Protection

Irrespective of the nature or the period of data protection granted to pharmaceuticals in general, fixed period data protection in case of traditional medicines should be provided for a period of ‘five years’. During this period each applicant would be required to submit complete data to the Drug Regulator. He shall rely on the data of the first applicant only for the purposes of comparison with the data submitted by the subsequent applicants.

There is no need for a separate definition for Traditional medicines – the present definition and concept where the Drugs and Cosmetics Act, 1940 appears to be appropriate.

Data Protection for traditional medicines should be granted for the following purposes -

- i) Data in support of new use or new dosage forms for traditionally used medication.**
- ii) Data generated in respect of standardization of products.**
- iii) Data generated for safety / efficacy / stability / quality / process standardization of an existing or a new product.**

Based on the above recommendations, the Ministry of Health and Family Welfare may carry out suitable modifications in Drugs and Cosmetics Act, 1940 / Drugs and Cosmetics Rules, 1945.

7.4.3. Data Protection for Pharmaceuticals:

As regards **pharmaceuticals**, schedule ‘Y’ of the Drugs and Cosmetics Rules, 1945 read with rules 122A, 122B, 122D, 122DA, 122DAA and 122E lays down the requirement of data for new drugs. It varies on whether for the international launching of a new drug the Originator seeks first marketing approval in India or

whether marketing approval sought is of a drug that has been marketed in another country for several years and adequate published data is available. In the first case elaborate preclinical and clinical test data needs to be submitted. In the latter case only limited data comprising of published data of the innovator and data of confirmatory clinical trials on a small number of patients and bioequivalence with the original drug. The term 'several years' in the Drug and Cosmetics Rules, 1945 would imply an extended period of time. However, since the period is not specified the marketing approval are being granted on the basis of published data and data in public domain as well as data generated in the country. Generation of detailed preclinical, phase –I, phase – II studies is not insisted upon in such cases under Rule 122(B) of Drugs and Cosmetics Rules, 1945

A look at the trend of drug approvals shows that most of the new drugs have been first launched in foreign countries. Thereafter these drugs are launched in India as generics. In the foreseeable future the same trend is likely to continue. For better data management and to ensure its confidentiality there is need to introduce the minimum requirements of Article 39.3 i.e. non-disclosure of test data and non-acceptance of fraudulently obtained data¹³. In the long run it may be in India's interest to move towards higher standards of data protection. However, before considering such option the Office of Drug Regulator needs critical upgradation in terms of physical infrastructure and technical skills. Constitution of a Central Drug Authority, an autonomous body with multiple technical skills and manpower is being set up by Ministry of Health and Family Welfare. A 'transitional period' should be considered for this purpose. During this transitional period, measures which are in the nature of minimum requirements of Article 39.3 can be implemented with the necessary legal changes. The duration of the transitional period need to be determined after further discussions.

Measures during the transitional period

The approach recommended for the transitional period is as below –

- a) **Drug Regulator to continue with the existing practice of approving new drugs as per the Drugs and Cosmetics Act, 1940 and Drugs and Cosmetics Rules, 1945 with suitable modifications.**

¹³ The Impact of Article 39.3 in India: A Practical Perspective – 1 – MAK Initiative for Medicine, access & Knowledge (July, 2006)

- b) Applicants may be asked to declare in their applications the ‘trade secret data’ that requires protection.
- c) Government should take adequate steps to ensure that specified undisclosed data submitted for seeking marketing approval for pharmaceutical products is not disclosed to any third party. Officials in the Office of Drug Controller General of India should be under an obligation to keep secret the undisclosed information submitted to Drug Regulator for approval of new drug.
- d) In case data has been obtained fraudulently by the second or ¹⁴ subsequent applicants it should be considered an unfair commercial use and should not be accepted by the Drug Regulator
- e) Any employee in the office of the Drug Regulator after ¹⁵ leaving employment should be barred from using the data of the Originator for getting any commercial advantage out of it
- f) Necessary improvements in data management may be adopted and best practices prevalent in other countries may be examined for adopting these in India. Physical infrastructure for safe storage of data needs to be considerably strengthened
- g) Liability of third parties in case of use without consent of the trade secret information, to be enforced through courts, should be clearly spelt out
- h) Central Government should have the power to disclose the trade secret information in exceptional circumstances in public interest.
- i) Although assistance of outside expert bodies like Indian Council of Medical Research and other national level medical institutions is taken by Drug Regulator for evaluation of new drugs, yet multidisciplinary expertise for this purpose must be created within the office of the Drug Regulator during the transitional period. The Central Drug Authority ¹⁶ being set up in India should have the required expertise for evaluation of the test data

¹⁴ }The impact of Article 39.3 in India:- A practical Perspective I –MAK , July, 2006

¹⁵ } -do-

¹⁶ Proposed structure of Central Drug Authority is indicated at Annexure 3.

k) The two provisos in sub-rule (3) of Rule 122B of the Drugs and Cosmetics Rules, 1945 empower the Drug Regulator to modify or relax generation of certain test data in case of new drugs approved and marketed for several years in other countries, if he is satisfied that there is adequate published evidence regarding the safety of the drug, subject to the other provisions of these rules. The term 'several years' needs to be clearly defined in the Rules. Thereafter, Drug Regulator should grant relaxation in the generation of test data only after the expiry of the specified time period.

For the purpose of introducing above provisions, suitable amendments need to be made in the Drugs and Cosmetics Act, 1940 and Drugs and Cosmetics Rules, 1945. Amendments on some of the points have been suggested by Dr N.S. Gopalakrishnan which are mentioned in Annexure –2. Other amendments as per the recommendations may be drafted by Ministry of Health and Family Welfare.

Suggested Model of Data Protection, for adoption in the post transition period :-

The feasibility of providing a fixed period data protection at a future date was deliberated upon. This could be for five years with the Drug Regulator not placing reliance upon the data submitted by the Originator while approving second and subsequent applications for the same product. After examining the views expressed for and against fixed term data protection by various stakeholders and experts a model has emerged which can be applicable with adequate safeguards in the post-transitional period. It is perceived that this model will help in early introduction of new drugs in India as also provide an impetus for R&D. However further analysis of the implications of this model is required.

Development of a new drug involves the following stages -

(i) *Chemical and Pharmaceutical Stage –*

Characterization of molecules, manufacturing and quality control standardization is done.

(ii) *Preclinical Safety and Efficacy Stage-*

In this stage the new chemical entity is tested in animals to assess its pharmacodynamic, pharmacokinetic and toxicological profile

iii) Clinical Safety and Efficacy Stage -

This stage includes the following phases:

Phase I - a small group of healthy volunteers is given the investigational drug for a¹⁷ short period of time to look for evidence of toxicity or unexpected undesirable reactions

Phase II - testing done on a small number of patients with the primary objective to¹⁸ ascertain the effectiveness of investigational drug

Phase III - conducted on a large number of patients, usually¹⁹ thousands, and are conducted for substantial periods. These tests are designed to determine the efficacy of the investigational drug and to uncover any unanticipated side effects that the drug may have, considering age and gender influence, drug interactions and specific dosage for different indications.

While the phase III trials are under way, long-term animal toxicity studies are²⁰ undertaken to determine the effects of prolonged exposure and the effects on subsequent generations. The duration of the studies vary widely among therapeutic classes. For drugs that affect the reproductive system or that will be used over long periods of time, animal toxicity studies are typically expensive and lengthy.

Phase IV or Post-marketing studies – After the launch of new drug in the market, its effect on patients in the hospitals is studied. This is part of pharmaco-vigilance. In India, this is carried out over a period of four years after launch of the new drug in the market.

Approximate time frame for approval of new drug/molecule in India -

Under the Indian law approval can be sought for a new drug/molecule in the following manner. The approximate time taken is mentioned against each stage –

¹⁷ Carlos Maria Correa – Protection of Data submitted for the Registration of Pharmaceuticals : Implementing the standards of the TRIPS Agreement.

¹⁸ - do -

¹⁹ - do -

²⁰ - do -

i) Originator, filing first application in India :

Examination time for data of preclinical, phase –I, phase – II and phase – III trials - 3 to 6 months for each phase.

Consultations with applicant and asking for fresh data - 1 to 2 months

Time taken for submission of fresh data by applicant - 6 to 12 months

Fresh examination by DR and approval – 2 to 3 months

It may take 5 to 6 years for development and approval of a new drug of an originator, though the time frame may differ widely based on the nature of drug and disease profile.

Note - Originator based in a foreign country is not permitted to conduct Phase–I clinical trials in India but is required to submit data of such trials conducted elsewhere.

ii) First applicant for a new drug in India which drug is already approved abroad.
In such cases, generation of elaborate test data in India is relaxed under rule 122(B) of the Drugs and Cosmetics Rules, 1945.

Time taken by DR for issuing full term NOC for BA/BE²¹, Phase-III clinical trials and CDL/CDTL²² testing by DCGI - 2 months

Time taken by applicant in Conducting BA/BE and Phase –III clinical trials - 4 to 8 months

Examination and marketing approval by DR - 2 to 3 months

iii) Subsequent Applicants for a new drug which is already approved in India:

Time taken for issue of NOC for BA/BE studies - 1 to 2 months

Time taken for conducting BA/ BE studies - 2 months

Examination and marketing approval by DR – 1 to 2 months

In the case of (ii) and (iii) above data requirements are fewer and therefore approval process is much shorter

²¹ Bioavailability / Bio-equivalence.

²² Central Drug Laboratory / Central Drug Testing Laboratory.

Features of the proposed model for fixed term data protection for adoption after the transitional period

(I) Definition of a New Chemical Entity-

A new drug under Rule 122 E of the Drugs and Cosmetics Rules, 1945 is as follows -

(a) A drug, as defined in the Act including bulk drug substance which has not been used in the country to any significant extent under the conditions prescribed, recommended or suggested in the labelling thereof and has not been recognized as effective and safe by the licensing authority mentioned under rule 21 for the proposed claims, provided that the limited use, if any, has been with the permission of the licensing authority.

(b) A drug already approved by the licensing authority mentioned in rule 21 for certain claims, which is now proposed to be marketed with

(c) A fixed dose combination of two or more drugs, individually approved earlier for certain claims, which are now proposed to be combined for the first time in a fixed ratio, or if the ratio of ingredients in an already marketed combination is proposed to be changed, with certain claims, viz., indications dosage, dosage form (including sustained release dosage form) and route of administration.(see items (b) and (c) of Appendix VI to Schedule Y).

Explanation – For the purpose of this rule –

- (i) all vaccines shall be new drugs unless certified otherwise by the licensing authority under rule 21;*
- (ii) a new drug shall continue to be considered as new drug for a period of four years from the date of its first approval or its inclusion in the Indian Pharmacopoeia whichever is earlier.*

The definition at Rule 122 E (a) can be considered as the definition of ‘NCE’ for drugs as and when this model is adopted.

In the alternative following definition is suggested —

‘A drug based on a new chemical entity which had no prior application for approval of the same drug in India or where the same drug or chemical entity was not previously known to commerce’. However following would be excluded from the definition of NCE –

- a) New indications.**
- b) New dosage forms.**

- c) **New combinations of two or more drugs.**
- d) **Polymorphs/ hydrates / solvates / isomers, salts, esters , metabolites, particle sizes, mixtures of isomers, complexes, chelates, mere admixtures or compositions etc of known substances unless they result in the significant enhancement of the known efficacy of that substance.**

- (iii) **The Drug Regulator will provide five years data protection to proprietary test data submitted by the Originator for obtaining marketing approval for a new drug which is a new chemical entity and actually relied upon by the Drug Regulator for that approval**

The Drug Regulator will not accord final approval to any subsequent applicant for that period of five years by relying on the data of the originator. This data protection and the non-reliance on such protected data would be subject to several safeguards as enumerated below.

Note – Proprietary data means the data that has not been published or known to the public at the time of or after its submission for marketing approval anywhere in the world.

Safeguards-

To avoid any adverse effects of this approach suitable safeguards may be provided in the interest of public health needs. These may be as under -

- i) The new chemical entities discovered after 1st January, 1995 only would be eligible for protection of test data for 5 years and this would be applied with prospective effect.
- ii) Protection should be provided to only New Chemical entities (NCE) not granted market approval by the Drug Regulator.
- iii) Protection shall apply to only undisclosed proprietary data and not to data already published or publicly available. Published and /or publicly available data comprises any information either available by way of use or made available either through publication in journals, symposiums, promotional literatures, information available on web-sites of various drug approving authorities and other related web sites of similar kinds.

iv) In the case of data protection for patented drugs, the period of protection should in no case go beyond the 20-year period of patent protection in India.

(v) The period of protection may be counted from the date of the first marketing approval anywhere in the world and the Originator must apply for marketing approval in India within 24 months of that date. The generic applicant in India can apply for marketing approval of the same drug in the following circumstances:

(a) Within 24 months of the date of first marketing approval of the drug anywhere in the world with the authorization of the Originator.

(b) After the period of 24 months has elapsed from the date of first marketing approval of the drug in the world. However, the generic applicant may apply prior to the expiry of 24 months for tentative marketing approval on his application, which will become final only after the day of the expiry of the 24 months if the Originator does not apply within this period. In case, the Originator applies within this period, the tentative approval will become final after the expiry of 5 years from the date of first marketing approval anywhere in the world.

Note: As part of post marketing surveillance as enumerated in Schedule 'Y' applicants of new drugs are required to furnish Periodic Safety Update Reports (PSURs) every six months for the first two years. For the subsequent two years PSURs are submitted annually. Thus, there is closer watch on safety of drug during the first two years. Thus, the suggested period of 24 months should give a fair indication of the safety of the drug.

(vi) Marketing approval of a new drug should cease to be valid if the product is not marketed within six months of its grant and if not marketed for twelve consecutive months at any time thereafter, and in consequence of such event Drug Regulator can grant marketing approval to second and subsequent applicants though the period of data protection may not have expired.

(vii) India should follow a system that will allow generic filing to be done during the Data Protection period as under Section 107 of Patent Act, 1970 (Bolar Provision). The Regulatory Authority could tentatively approve the generic product during the period of data protection if it meets various regulatory requirements. Generic companies should be allowed to initiate the application procedures and required studies, during the data protection period, in order to start commercializing

immediately after the expiry of the data protection period. The approval will automatically become final the day following the expiry of the data protection period.

(viii) Provisions like sections from 84 to 92A (compulsory license) of the Patents Act, 1970 should be introduced in the relevant laws and these should override the provision for data protection. In case of a patented drug if compulsory licence has been issued there would be automatic waiver of data protection.

(ix) The Drug Regulatory Authority for authorising marketing of new drugs shall be free to determine the requirement of data from the first applicant.

(x) Government shall have the right to waive off all or any provision pertaining to data protection in case of a public health emergency. In such a situation, the Drug Regulator would be free to grant marketing approval to subsequent applicant/s based on published data and limited test data generated in India.

(xi) In cases where repeating the clinical trials for a drug is not considered essential, the Regulatory Authority may allow marketing approval to subsequent applicants of a drug similar to an earlier approved drug by placing reliance on the first applicant's undisclosed data .

(xii) Government shall have the right to create a suitable mechanism of price negotiations to ensure that the prices of new drugs are reasonable for fulfilling the affordability and accessibility criteria in the public interest.

(xiii) The provisions relating to data protection shall not restrain manufacture for export to countries, which either do not have provision for data protection or where the term of protection has expired. In other words the protection would only be available for marketing of drugs within the territory of India.

Note: Applicant will be required to inform the Drug Regulator with evidence about the date of launch of the drug in India.

Exemptions-

Drugs for life threatening diseases like HIV / AIDS may be exempted from the provisions of fixed period data protection as mentioned above i.e the Drug Regulator may place reliance on the data submitted by the first applicant in India/ foreign

country and grant market approval to subsequent applicants for same product in India .

**No.11025/7/2003-PI-II
Government of India
Ministry of Chemicals and Fertilizers
(Department of Chemicals and Petrochemicals)**

New Delhi, the 19th February , 2004.

Office Memorandum

Sub: Protection of Undisclosed information-Article 39.3 of the TRIPS Agreement

In order to consider the steps to be taken by the Government in the context of the provisions of Article 39.3 of the TRIPS Agreement for the protection of undisclosed information, it has been decided to constitute a Committee with the following members:-

- | | | |
|------|---|-----------|
| (1) | Secretary, Department of Chemicals and Petrochemicals | Chairman |
| (2) | Joint Secretary, Department of Commerce | ...Member |
| (3) | Joint Secretary, Department of IPP | ...Member |
| (4) | Joint Secretary, Department of Health | ...Member |
| (5) | Joint Secretary, Department of Agriculture | ...Member |
| (6) | Joint Secretary, Department of Science and Technology | ...Member |
| (7) | Joint Secretary, Department of Bio-technology | ...Member |
| (8) | Joint Secretary, Department of Scientific and Industrial Research .. | ...Member |
| (9) | Joint Secretary, Department of Legal Affairs | ...Member |
| (10) | Joint Secretary(Chemicals), Deptt of C&PC | ...Member |
| (11) | Dr. Biswajit Dhar, Prof. & Head, Centre for WTO Studies, IIFT, New Delhi | ...Member |
| (12) | Shri Praveen Anand, Advocate, M/s Anand & Anand, New Delhi | ...Member |
| (13) | Ms. Pallavi Shroff, ...
M/s Amarchand Mangaldas & Suresh Shroff & CO, N. Delhi | ...Member |
| (14) | Shri Ashwini Kumar, DCGI, Ministry of Health, New Delhi | ...Member |
| (15) | Shri Y.Tsering, Secretary, Central Insecticides Board & Director, Deptt of Agriculture & Cooperation, New Delhi | ...Member |

2. The Committee would, inter alia, look at whether data protection can be offered under the existing legal provisions or an appropriate new dispensation is required for this purpose.

(sd\ -)
(Arvind Singh)
Director

Views of Dr. N.S. Gopalakrishnan

Department of Commerce had asked Dr. N.S. Gopalakrishnan of Centre for Intellectual Property Rights Studies, Cochin to undertake a study to identify the suitable mode of protection of test data in India considering the interest of the Indian industry, while complying with the TRIPS obligations. In his report Dr. Gopalakrishnan has suggested the following:

- a) Mandatory provision for ensuring the safety and quality of drugs;
- b) Power of the DCGI to demand undisclosed information for drug approval for manufacture or import;
- a) Limit the data requirement to new drugs that are introduced first in India and not available in the market anywhere in the world;
- b) Provision creating obligation on the part of the officials in the office of Drug Controller General of India (DCGI) to keep the undisclosed information submitted to the DCGI for approval of a new drug is secret;
- c) Obligation of the person submitting data to declare the status and nature of the information that require protection;
- d) Power of the Central Government to disclose this information on public interest;
- e) Liability of persons in the office of DCGI under the Official Secret Act, 1923 in case of unauthorized disclosure of the secret information;
- f) Liability of the third parties in case of use of this information without the consent of the parties.

Similar provisions can be included in Insecticides Act also.

Proposed Amendments to the Drugs and Cosmetic Act:

(Note: We are introducing this new section to make express provision in the Act for drug approval which as of now is only in the Rules. This is needed since we are suggesting undisclosed information form of protection for test data submitted for approval of new drugs with liability on the officials disclosing it and third parties using the same).

Add new Section 18A

Section 18A Prohibition and liability for disclosure of information:

- (1) No person shall be entitled to the license under the section (c) of Section 10 or under sub section (c) of section 18 for a drug unless approved by the licensing authorities in accordance with the Rules prescribed under this Act.

(2) For the purpose of approval under subsection (1) the licensing authorities may insist on the submission of any information to be considered as undisclosed by the applicant.

(3) The licensing authority insisting on submission of information under sub-clause

(4) For new drugs shall keep such information as undisclosed by the applicant.

(5) Provided that the government may by notification direct the authority to disclose such information in public interest based on such terms and conditions as it may deem fit.

(6) Any person violating the breach of confidence under subsection (3) may be liable to be prosecuted under the Official Secret Act, 1923.

(7) The applicant under subsection (1) shall be entitled to injunction, compensation or account of profit from any person using the information submitted under subsection (3) in violation of breach of confidence.

Proposed Amendments to the Drugs and Cosmetics Rules, 1945

Amendments to Rule 122-A (Amendment in bold letter)

(1)

(2) The importer of a new drug that is not approved or marketed in other countries when applying for permission under sub-rule (1) shall submit data as given in Appendix 1 to Schedule Y including the results of local clinical trials in the format given in Appendix II to the said Schedule.

Provided that in case of new drugs already approved or marketed in other countries or there is adequate published evidence regarding the safety of the drug, the importer shall submit only data of local clinical trial as given in Appendix I to Schedule Y carried out in accordance with the guidelines specified in that Schedule.

Provided further that the requirement of submitting the results of local trials may not be necessary if the drug is of such a nature that the licensing authority may in public interest decide to grant such permission on the basis of data available from other countries.

Delete last proviso

Amendments to Rule 122-B (Amendments in bold letters)

(1).....

(2) The manufacturer of a new drug that is not approved or marketed in other countries under sub-rule (1) when applying for approval to the licensing authority

mentioned in the said sub-rule, shall submit data as given in appendix I to Schedule Y including the results of clinical trials carried out in the country in accordance with the guidelines specified in Schedule Y and submit the report of such clinical trials in the format given in Appendix II of the said Schedule.

Provided that in case of new drugs already approved or marketed in other countries or there is adequate published evidence regarding the safety of the drug, the manufacturer shall submit only data of local clinical trial as given in Appendix I to Schedule Y carried out in accordance with the guidelines specified in that Schedule.

Provided further that in case of subsequent approval for already approved new drugs as per sub-rule(1) the manufacture shall submit only data as provided in Appendix I-A of Schedule Y.

(3).....

Delete second proviso in 122-B(3).

Amendments to Form 44

Add the following after (2)I() (3).....

3. Specify the data that require protection as per section 18A(3) of the Act.

4. Certified that the data specified in column 3 is data generated by us and is not disclosed to any one. This data is also not publicly available from any other source.

CENTRAL DRUG AUTHORITY

DRUG CONTROLLER GENERAL (INDIA)

Drug Technical Advisory Board

Drug Consultative Committee

OFFICE - 1

OFFICE - 2

OFFICE - 3

Regulatory Affairs & Enforcement	Division for imports
----------------------------------	----------------------

New Drug & Clinical Trials Enforcement	Biologicals & Biotechnology Products	Pharmaco Vigilance	Medical Devices and Diagnostics
--	--------------------------------------	--------------------	---------------------------------

Organisational Services	Training & Services	Quality Control Affairs	Legal and Consumer Affairs
-------------------------	---------------------	-------------------------	----------------------------

Drug Technical Advisory Board Drug Constative Committee	Registration of Overseas Manufacturers
Central Licensing	Overseas Inspections
Zonal / Suib Zonal and State Offices	Manging Port Offices
Inspections (domestic & International)	Import Licenses
Guidelines and Directives	Quality Monitoring of Imported Products
Interstate Issues	
Drug Recalls	
Investigations	
Regulations of Promotion of Medicines & Product Information	
Legal Affairs	
International Cooperation	
Exports	

Clinical Trials approval (Including regulations and registrations of investigation sites, ethics Committee & Investigation	Vaccines & Sera (Human & veterinary)	Safety Monitoring of Drugs and Devices	Devices Evaluation
Regulatory Inspection of C/T sites, sponsor sites and ethics Committee	Blood & blood Products	National Pharmaco Vigelense Advisory Committee	Diagnostics Evaluation
Efficasy & safety evaluation of new Drugs including INDs.	Recombinational & other Biotechnology Products	National, Zonal , Regional Peripherral Pharmaco Vigelence Centers	Licensing and Enforcement
Pharmaceutical Quality evaluation			Imports
Biostatistics			
Vertinary new Drugs			
Issues Related to border line products			
Screening of marketing drug formulations			

Administerial Matters	Planning & Forcasting	Manging Central drug Laboroteries	Cour Caeses
Accounts	Training	Monitoring of State and Private labs	Parlimetary Affairs
Planning & finance	Evaluation & Impact Assesment	Audits (Including proficiency testing) and accreditation	NDPS
Information Technology		Drug Standards	Consumer Information (Health Care)
		Indian Pharmacopia	Public Compliants
		International Harmonisation	Licensee's Information
			Website
			Press & Public Relation
			Implmentation of Drugs and Magic Remedies (DMR)