Main Identity

From: "Naveen" <navthom@gmail.com>
To: <aidanindia@yahoogroups.com>
Cc: <chc@sochara.org>; "ravi" <ravi@phmovement.org>
Sent: Monday, June 26, 2006 6:16 PM
Attach: AIDAN Response_Data Exclusivity.doc
Subject: Data exclusivity

Dear friends,

I read that the PMO has called the Ministries of Health, Commerce, Chemicals and Fertilisers, Science and Technology and the Centre for Scientific and Industrial Research (CSIR) on July 12, 2006 for a meeting to decide about amending the Drug and Cosmetics Act.

The purpose of the amendment is to include 'data exclusivity' which would make it mandatory for generic companies in India to conduct their own clinical trials before marketing a drug during the period of the data exclusivity. The other possible impacts are listed in the attached document.

Shouldn't we send out comments to the respective ministries and PMO as AIDAN? I have attached a draft letter with comments on the issue. Please give your comments/ or modify it suitably. We can also send it from our respective organisations.

Looking forward to your responses.

Best wishes,
Naveen
CHC

July 3, 2006

Comments on the Proposed Amendment to the Drug and Cosmetics Act, and the issue of Data Exclusivity by *Jan Swasthya Abhiyan* (JSA)

The Jan Swasthya Abhiyan (JSA) is the Indian circle of the People's Health Movement, a worldwide movement to establish health and equitable development as top priorities through comprehensive primary health care and action on the social determinants of health. The JSA coalition consists of over 20 networks and 1000 organisations as well as a large number of individuals that endorse the Indian People's Health Charter a consensus document that arose out of the Jan Swasthya Sabha held in December 2000.

We are writing this letter to share our strong concerns on the issue of 'Data Exclusivity' and its inclusion in the proposed amendment to the Drug and Cosmetics Act. **We consider 'data exclusivity' to be another attack on peoples' health.** We urge you to consider these concerns and stop any move to amend the above Act, or to include 'Data Exclusivity' in any legislation. Looking forward to your early action in this regard. In case you need more information, we would be happy to provide the same.

OUR CONCERNS ON THE ISSUE OF DATA EXCLUSIVITY

1) **The TRIPS agreement does not refer to any period of data protection, nor does it refer to data exclusivity.**
2) **This move to include 'data exclusivity' is a 'TRIPS-plus' agenda which is anti-people and against people's interest. It is being pushed by vested interests including large Multi-National Corporations and certain foreign governments.**
3) **Data exclusivity has become a means of preventing competition from Indian manufacturers which greatly restricts access to medicines.**
4) **It is unethical to conduct clinical trials on drugs which have already been proven effective.**
5) **The cost of generic drugs and the costs of health care are bound to increase, which is a wasteful expenditure which a country like ours can ill-afford.**
6) **The civil society in the country and even experts from within the Government have opposed the amendment because of the impact it will have on people and people's access to medicines.**

Compliance with TRIPS

In complying with the TRIPS norms, India amended the Indian Patents Act, 1970 for the second time as recently as two years back against much public opposition. This move to further alter Indian legislation to supposedly comply with TRIPS requirements is an unwarranted step. **In fact, the TRIPS agreement does not refer to any period of data protection, nor does it refer to data exclusivity.**

Article 39.3 of TRIPS says that WTO Members should protect "undisclosed test or other data" against "unfair commercial use" and "disclosure". Nowhere does TRIPS state that countries should provide *exclusive* rights to the originator of the data for a *given* period. Rather, TRIPS simply refers generally to the need for "data protection".[i]

Data protection against unfair commercial misuse as mentioned in TRIPS is totally different from data exclusivity. The use of data by the Drug Controller to compare bioavailability and bioequivalence data is a legitimate, non-commercial use and is TRIPS compliant.

TRIPS plus – An Anti-People Agenda

Preventing comparative use of data submitted for getting marketing license from the Drug Controller is definitely a TRIPS PLUS measure. Such measures are being forced on developing countries as part of many of many Free Trade Agreements and Bilateral Trade Agreements.

In fact, the Report of the Commission on Intellectual Property Rights, Innovation and Public Health (CIPRIPH), of which Dr. R. A. Mashelkar was the Vice-Chairperson has clearly **cautioned countries** from placing unnecessary data protection norms. In page 143, it clearly says *"Article 39.3, unlike the case of patents, does not require the provision of specific forms of rights. [...] It does not create property rights, nor a right to prevent others from relying on the data for the marketing approval of the same product by a third party, or from using the data except when unfair (dishonest) commercial practices are involved."* In page 144, it states, *".....developing countries should not impose restrictions for the use of or reliance on such data in ways that would exclude fair competition or impede the use of flexibilities built into TRIPS".*[ii]

Access to Drugs

It is clear that data exclusivity could prevent the registration of generic versions of medicines even when there is no patent on a medicine. For instance when a pharmaceutical does not meet the standards for patentability or when no patents are granted for pharmaceuticals, the data could still come under 'data exclusivity' norms.[iii] Data exclusivity has thus become a means of preventing competition from Indian manufacturers which greatly restricts access to medicines.

As the Global AIDS Alliance and the others working on 'access to drugs' have pointed out, such amendments will have **adverse effects on the global availability of affordable essential medicines** meant to treat HIV/AIDS, hypertension, diabetes, asthma and many other diseases. If 'data exclusivity' is applied, then companies would be prevented from taking marketing approval even if they have been granted compulsory license to use a patented substance during the period the data exclusivity is in operation.

Unethical Practice

In addition to all the above problems, **data exclusivity raises very important ethical questions**. Entities desirous of making a generic drug would have to repeat clinical trials, which would be unethical as they would be conducting efficacy trials with compounds which have already been proven effective, while denying effective drugs to certain other people.

Health Care Costs

In a country where most of the spending on health is through out-of-pocket expenditure and the provision of government services is limited, any increase in cost of drugs is bound to adversely affect people's access to drugs. A duplication of clinical trials is **bound to increase the cost of drugs and is a wasteful expenditure** which a country like ours can ill-afford. As the Report of the CIPRIPH states, the United Nations Special Rapporteur on the Right to Health commented on the possible additional health-care costs relating to the introduction of data exclusivity in the Free Trade Agreement between the United States and Andean Pact countries.

Mismatched Responsibilities

The drug regulatory authority is a body set up as a public authority. Its function is to ensure, in public interest, that drugs that are provided with marketing approval meet the criteria of safety, efficacy and good quality. Drug Regulatory Authorities need be concerned with safety and efficacy of a drug, and are not supposed to involve themselves with the patent status of a drug. By amending the Drugs and Cosmetics Act, **Drug Regulatory Authorities will be required to look at the Patent status of a drug, which does not fall under their domain**. Under the guise of Data Exclusivity, what is really being sought is that drug regulatory authorities should act on behalf of pharmaceutical companies to safeguard their monopoly right.[iv]

The recent WHO Briefing Note on Access to Medicines emphatically states that efforts to integrate the intellectual property system and the drug regulatory system via data exclusivity, "linkage" or other means are

likely to have negative implications for access to medicines. It calls on countries to keep these systems separate, and to reject any and all efforts to make connections between them.

Opposition from Within

Experts on the issue, including experts from civil society, the Parliament Standing Committee on Commerce and the Ministries of Commerce and Health have **opposed the amendment** because of the impact it will have on people's access to drugs and agro-chemical products. These views should be taken into account while taking a decision of such far-reaching impact.

What is the Alternative?

Instead of seeking to further expand the scope and duration of 'exclusive rights' of drugs and agro-chemical products, India should seek to **encourage competition from Indian manufacturers**.

A minor addition to the Drugs and Cosmetics Act which says 'test data provided by a company will not be made public or shared with its potential competitors for five years' is enough to meet the requirements of TRIPS. This does not prevent the Drug Regulatory Authorities from relying on the data to license a generic version of a new drug.

The urgent need of the hour is **to improve people's access to drugs and to make drugs affordable**. We hope these issues will be taken up strongly in the new Drug Policy.

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[i] *Data exclusivity in international trade agreements: What consequences for access to medicines?* MSF Technical Brief - Campaign for Access to Essential Medicines, 2004.

[ii] *Public health, Innovation and Intellectual Property Rights* - Report of the Commission on Intellectual Property Rights, Innovation and Public Health, WHO, 2006.

[iii] *Briefing Note – Access to Medicines*, World Health Organisation (WHO Regional Office for South East Asia and WHO Western Pacific Region), 2006.

[iv] *Data Exclusivity: Implications for Public Health*, Amit Sen Gupta, 2006.

29 June 2006

Draft Comments on the Proposed Amendment to the Drug and Cosmetics Act, and the issue of Data Exclusivity by Community Health Cell (CHC)

Community Health Cell (CHC) is a technical resource group in health. We have been involved in community health, public health and health policy issues for the past twenty-two years. Promoting community health based on the social paradigm, through policy action, training, mainstreaming, networking and the people's health movement is CHC's core thrust. CHC recognises that peoples' health is deeply influenced by determinants that are ~~deeply~~ embedded in the social, political, economic, cultural and ecological fabric of life.

We are writing this letter to share our concerns on the issue of 'Data Exclusivity' and its inclusion in the proposed amendment to the Drug and Cosmetics Act.

OUR CONCERNS ON THE ISSUE OF DATA EXCLUSIVITY

1) **The TRIPS agreement does not refer to any period of data protection, nor does it refer to data exclusivity.**
2) **This move to include 'data exclusivity' is a 'TRIPS-plus' agenda which is anti-people and against people's interest. It is being pushed by vested interests including large Multi-National Corporations and certain foreign governments.**
3) **Data exclusivity has thus become a means of preventing generic competition which greatly restricts access to medicines.**
4) **It is unethical to conduct clinical trials on drugs which have already been proven effective.**
5) **The cost of generic drugs and the costs of health care are bound to increase, which is a wasteful expenditure which a country like ours can ill-afford.**
6) **The civil society in the country and even experts from within the Government have opposed the amendment because of the impact it will have on people and people's access to medicines.**

Compliance with TRIPS

In complying with the TRIPS norms, India amended the Indian Patents Act, 1970 for the second time as recently as two years back against much public opposition. This move to further alter Indian legislation to supposedly comply with TRIPS requirements is an unwarranted step. **In fact, the TRIPS agreement does not refer to any period of data protection, nor does it refer to data exclusivity.**

Article 39.3 of TRIPS says that WTO Members should protect "undisclosed test or other data" against "unfair commercial use" and "disclosure". Nowhere does TRIPS state that countries should provide *exclusive* rights to the originator of the data for a *given* period. Rather, TRIPS simply refers generally to the need for "data protection".[i]

TRIPS plus – An Anti-People Agenda

The Report of the Commission on Intellectual Property Rights, Innovation and Public Health (CIPRIPH), of which Dr. R. A. Mashelkar was the Vice-Chairperson has clearly cautioned countries from placing unnecessary data protection norms. In page 144, it states, "*.....developing countries should not impose restrictions for the use of or reliance on such data in ways that would exclude fair competition or impede the use of flexibilities built into TRIPS*". It further states in page 147 that *"facilitating the entry of generic competition after the expiry of a patent is one means of potentially bringing down the price of health-care products".*[ii]

Access to Drugs

It is clear that data exclusivity could prevent the registration of generic versions of medicines even when there is no patent on a medicine. For instance when a pharmaceutical does not meet the standards for patentability or when no patents are granted for pharmaceuticals, the data could still come under 'data exclusivity' norms.[iii] Data exclusivity has thus become a means of preventing generic competition which greatly restricts access to medicines.

As the Global AIDS Alliance and the others working on 'access to drugs' have pointed out, such amendments will have adverse effects on the global availability of affordable essential medicines meant to treat HIV/AIDS, hypertension, diabetes, asthma and many other diseases. If 'data exclusivity' is applied, then companies would be prevented from taking marketing approval even if they have been granted compulsory license to use a patented substance during the period the data exclusivity is in operation.

Unethical Practice

In addition to all the above problems, data exclusivity raises very important ethical questions. Entities desirous of making a generic drug would have to repeat clinical trials, which would be unethical as they would be conducting efficacy trials with compounds which have already been proven effective, while denying effective drugs to certain other people.

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In a country where most of the spending on health is through out-of-pocket expenditure and the provision of government services is limited, any increase in cost of drugs is bound to adversely affect people's access to drugs. A duplication of clinical trials is bound to increase the cost of drugs and is a wasteful expenditure which a country like ours can ill-afford. As the Report of the CIPRIPH states, the United Nations Special Rapporteur on the Right to Health commented on the possible additional health-care costs relating to the introduction of data exclusivity in the Free Trade Agreement between the United States and Andean Pact countries.

Opposition from Within

Experts on the issue, including experts from civil society and the Ministries of Commerce and Health have opposed the amendment because of the impact it will have on people's access to drugs and agro-chemical products. These views should be taken into account while taking a decision of such far-reaching impact.

What is the Alternative?

Instead of seeking to further expand the scope and duration of 'exclusive rights' of drugs and agro-chemical products, India should seek to encourage generic entry on patent expiry. One such norm which is presented in CIPRIPH, and practiced in countries like Canada is the "early working" exception. This is consistent with the TRIPS Agreement and allows prospective generic producers to make use of a patented product within the patent period for the purposes of obtaining regulatory approval of their product as soon as the patent expires. The "early working" exception constitutes jointly, with parallel imports and compulsory licenses, one of the flexibilities ~~that~~ under the TRIPS agreement.

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[i] *Data exclusivity in international trade agreements: What consequences for access to medicines?* MSF Technical Brief - Campaign for Access to Essential Medicines, 2004.

[ii] *Public health, Innovation and Intellectual Property Rights* - Report of the Commission on Intellectual Property Rights, Innovation and Public Health, WHO, 2006.

[iii] *Briefing Note – Access to Medicines*, World Health Organisation (WHO Regional Office for South East Asia and WHO Western Pacific Region), 2006.

----- Original Message -----
From: Naveen
To: pha-ncc@yahoogroups.com
Sent: Thursday, June 29, 2006 11:57 AM
Subject: Defeat the anti-generics move of the Govt.

Dear friends,

The Prime Minister's Office has called the Ministries of Health, Commerce, Chemicals and Fertilisers, Science and Technology and the Centre for Scientific and Industrial Research (CSIR) on July 12, 2006 for a meeting to decide about amending the Drug and Cosmetics Act.

The purpose of the amendment is to include 'data exclusivity' which would make it mandatory for generic companies in India to conduct their own clinical trials before marketing a drug during the period of the data exclusivity. This is another gimmick of the pharma companies to extend their protection and to prevent generic competition. They are using the TRIPS agreement as the basis of their demand.

India already passed the Patent's Amendment Act to comply with the TRIPS agreement. Now, this amendment in the Drug and Cosmetics Act wants to include clauses which goes even beyond the agreement. In fact the TRIPS agreement does not refer to data exclusivity. The WHO Commission on Intellectual Property Rights, Innovation and Public Health (CIPRIPH), of which Dr. R. A. Mashelkar was the Vice-Chairperson has also reiterated this fact. The civil society in the country and even experts from within the Government have opposed the amendment because of the impact it will have on people and people's access to drugs.

As JSA we must strongly protest this move of the Government. It will be useful if we can send letters to the concerned ministries expressing our concern.

Looking forward to your responses.

Best wishes,
Naveen

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Naveen I. Thomas
Community Health Cell (CHC)
No. 359 (Old No. 367), Srinivasa Nilaya
Jakkasandra, 1st Main
1st Block, Koramangala
Bangalore - 560 034. India
Tel: +91-(0) 80-25531518
Telefax: +91-(0) 80-25525372
Email: navthom@yahoo.co.uk
Website: www.sochara.org

NT
Saw both documents. Succinct and comprehensive and well done! Keep it up

RH
3/7/06

Sl. No.	Name / [redacted]	Contact phon Number Email ID
1	Deepak / 25471680 / 25461920	SPAD
2	REBECCA DESOUZA	PURDUE rdesouza@purdue.edu
3	Hamza. C. 25430155	Freedom Foundation. Bangalore.
4)	Diwakara. S	Freedom Foundation Bangalore.
5)	NATARAJ. S. 22714110	ACCEPT, Bangalore 56990452
6.	DR. MANISH 25586682	ABHAYA, ACTIONAID, BANGALORE
7.	Meghna Girish	ActionAid, HIV Thematic Team
8.	S. Radha	SAMRAKSA. 26604563 / 26577638
9.	Vidyuth.	Lawyers Collective
10	Vidyalatha	Samraksha.
11	Regina	Samraksha
12	Anil M. Lobo	Prerana.
13.	T. Charles Allwin	charlesallwin@hotmail.com Ph: 25634185
14	M. S. Christopher	icyebl r@vsnl.com. Cell: 9844459923
15	Mary Bosco 23566601/02/03	KHPT
16	Varsha. R. Iyengar	varsha.iyengar@gmail.com. Lawyers Collective
13.	Lakshmi	
14.	Prasanna Saligram	AID India.
15.	Naveen Thomas	navthom@yahoo.co.uk ; 9342858856.
16	Asha.	Lawyers Collective
17.	Arti Malik	Lawyers Collective
18.	Rajakumar	"
19.	Chan Park	"
20.	Ramaiya	"

----- Original Message -----
From: Amitava Guha
To: Naveen ; Amit Sen Gupta ; mirashiva@yahoo.com
Sent: Friday, June 30, 2006 1:11 PM
Subject: Re: Data Exclusivity

Dear Navin,
Thank you for your mail. You have pointed out an important issue where we need to go for an immediate action. I personally feel that data exclusivity should not be allowed. whatever expenses the MNCs make for safety, efficacy and toxicology study is extracted out by keeping the prices of patented medicines very high. Thus they recover the expensed within two years maximum of introduction of new medicine.
In some countries data exclusivity is allowed till the patent period lasts but is not applicable for early working of a patented molecule.
I am not very sure how Indian industry is reacting but in their recent actions they are found to be useless. I am contacting the National Working Group, if they are planning some actions.
FMRAI would like to join actions with pothers. I shall talk with our Bangalore unit
friends requesting them to jointly work with you. Our Bangalore unit is not very strong since most of the field workers here are very new.
You may contact our unit secretary in the following address.
A.K Suresh
1530, 11th Main, Vijayanagar
Bangalore-560 040 Phones: 080-23404179; 9448858897

Best Wishes,
Amitava

World Health Organization
Regional Office for South-East Asia

Briefing Note
Access to Medicines

World Health Organization
Western Pacific Region

March 2006

DATA EXCLUSIVITY AND OTHER "TRIPS-PLUS" MEASURES

REGULATING MEDICINES

The pharmaceutical market is highly regulated. Two sets of laws and regulations play a crucial role in this market. These are i) the intellectual property laws and ii) the laws and regulations about drug registration. These two sets of laws have different objectives, and are administered by different government agencies.

Intellectual property rights, notably patents (on which this briefing note will focus, since they have the most profound implications on access to medicines) are meant to reward innovation by providing inventors with temporary monopoly rights. Patents, however, confer negative rights: a patent on a certain pharmaceutical product means that the patent holder can prevent others from producing or selling that product. But it does not give the patent holder the right to actually sell that medicine. In order to be allowed to sell a medicine, it has to be registered by the national Drug Regulatory Authority.

The drug regulatory system, or registration system, seeks to ensure that only medicines of assured safety, quality and efficacy are available on the national market. This is important, since consumers do not normally have sufficient information and knowledge about a pharmaceutical product to make their own assessment about its quality, safety and efficacy. In addition, medicines that are ineffective or of poor quality can be dangerous, both for the patient and for public health.

In order to assess the quality, safety and efficacy of a product, the Drug Regulatory Authority will normally require the manufacturer to provide relevant information. For instance, in order to assess the quality of the product, samples will have to be tested, the production procedures will have to be documented and validated, and the production facility may have to be inspected.

Meanwhile, the safety and efficacy of pharmaceuticals is demonstrated mainly via pre-clinical and clinical trials. Safety and efficacy can also be demonstrated by showing that a product is chemically and biologically equivalent to an existing medicine (the safety and efficacy of which are already known). However, by definition, 'bio-equivalence' can *not* be demonstrated for entirely *new* pharmaceuticals, since there will be no similar existing medicines with which to compare them. Thus, in practice, only generic manufacturers can demonstrate the safety and efficacy of their products via bio-equivalence tests.

This latter point is important, since bio-equivalence tests are much smaller in scale than full-fledged clinical and pre-clinical trials. Thus, they can be conducted faster, and are considerably less expensive.

DATA EXCLUSIVITY

The clinical and pre-clinical trial data that originator companies submit to the Regulatory Authority are at the centre of the debate on "data exclusivity".

Because bio-equivalence data only prove that a generic medicine behaves in the body in the same way as the original product (the safety and efficacy of which have already been established), one could say that the generic company and the Regulatory Authority indirectly rely on the clinical trial data provided by the originator company.

Originator companies argue that, since they made substantial investment in these trials, they deserve a period of "data exclusivity"; a certain length of time during which the Regulatory Authority cannot rely on the originator's data in order to register a generic version of the same product.

By implication, as long as the exclusivity lasts, generic producers would have to submit their own data to prove safety and efficacy, which would oblige them to repeat the clinical trials and other tests. This is something that would cause significant delay, and that many generic manufacturers cannot afford. Moreover, it would raise serious ethical questions, since it would mean that clinical trials will have to be repeated, purely for commercial reasons.

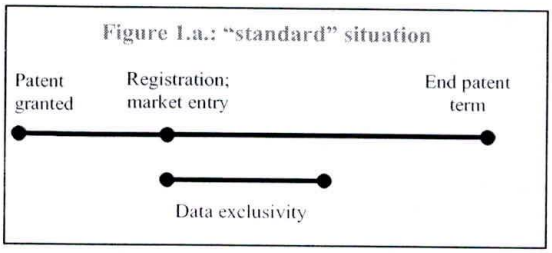
Alternatively –and in practice much more likely– generic producers would have to delay the launch of their product until the end of the exclusivity period[1]. Thus, data exclusivity diminishes the likelihood of speedy marketing of generics, and delays competition and price reductions.

[1] In the United States, data exclusivity lasts five years for new chemical entities and three years for new indications. In the European Union, it is 10 years with a possible one year extension in case the drug is registered for a significant new indication.

Implications of Data Exclusivity

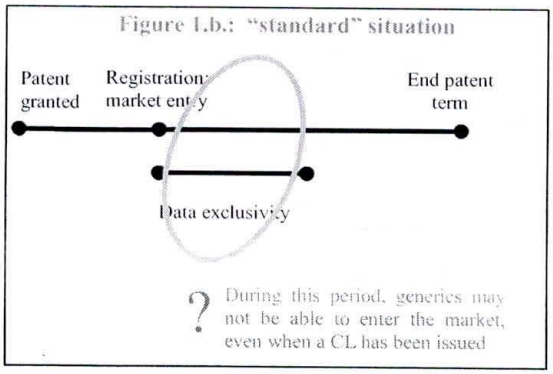
Proponents of data exclusivity at times point out that data exclusivity does not have major implications, since the period of data exclusivity would normally be shorter than the patent duration (see Figure 1a).

Figure 1.a.: "standard" situation



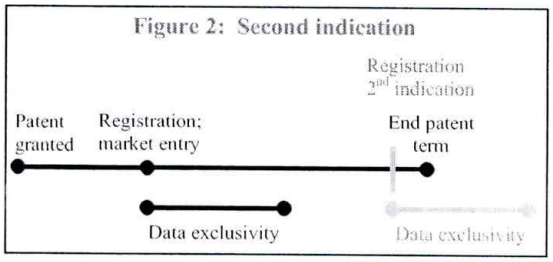
Yet, there are some questions as to whether data exclusivity could prevent the registration of medicines produced under a compulsory license (see Figure 1b). If so, data exclusivity would effectively render the compulsory license useless.

Figure 1.b.: "standard" situation



Secondly, if a period of data exclusivity is also granted when an existing medicine obtains marketing authorization (or registration) for a second or new indication, data exclusivity could (be used to) extend the period of exclusivity of the originator product (see Figure 2).

Figure 2: Second indication



Finally, data exclusivity could prevent the registration of generic versions of medicines even when there is no patent on a medicine, for example when a pharmaceutical does not meet the standards for patentability (e.g. because it is not new), when a country has no patent law, or when no patents are granted for pharmaceuticals. The latter situation can arise in least-developed World Trade Organization (WTO) Member Countries, which do not have to grant patents for pharmaceuticals until 2016.[2]

TRIPS does not require Data Exclusivity

It has at times been argued that Article 39.3 of the TRIPS Agreement makes it mandatory for countries to grant data exclusivity. However, careful reading of Article 39.3 (see Box 3) does not warrant this conclusion; the text of the Article does not make any reference whatsoever to exclusivity or exclusive rights.

Article 39.3 requires countries to protect undisclosed registration data about new chemical entities i) against disclosure and ii) against unfair commercial use. Thus, regulatory authorities may not publish registration data[3], or share them with third parties (e.g. generic competitors). This is a clear requirement. But there is some debate as to what exactly is meant by 'unfair commercial use'. Does the use of bio-equivalence studies instead of full clinical trials represent 'unfair commercial use'?

Clearly, there is no 'unfair commercial use' by the generic company. The generic manufacturer never uses the originator's data, and does not even have access to them. Meanwhile, the regulatory authorities also do not normally use the originator's data – though, as mentioned above, they may (indirectly) rely on them. But even if the regulators would use those data, this is not commercial use, since the regulatory agency is not a commercial organization. Legal experts have also pointed out that, in the context of Article 39 of TRIPS, the term 'unfair commercial use' refers to, and prohibits, practices such as industrial espionage, but was not meant to provide exclusive rights (Correa, 2002). Nor was it meant to interfere with the work of a government body tasked with protecting the public.

Thus, legal and public health experts believe that TRIPS requires data protection, but not data exclusivity – and national laws do not need to be more stringent or more restrictive than TRIPS.

Box 3: Article 39.3 of TRIPS

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.

[2] According to the Declaration on the TRIPS Agreement and Public Health, WTO Ministerial Conference, Doha, Nov. 2001 (or the "Doha Declaration").

[3] Though it is important to note that they may do so when this is necessary to protect the public.

It is also worthwhile to note that in developing countries, regulatory authorities often rely on data that are already published or otherwise in the public domain – and that therefore do not fall within the scope of Article 39.3 (which only imposes protection for *undisclosed* data).

Mitigating the Impact

As mentioned above, from the perspective of public health and access to medicines, it is preferable not to grant data exclusivity. Moreover, there is no requirement under international law that countries grant data exclusivity; countries only have to provide for data protection.

But if a country, for some reason (see below), *does* grant data exclusivity or otherwise provides data protection beyond that mandated by TRIPS, it is important to limit its potential negative implications on access to medicines. This can for example be done by limiting its duration and/or scope (e.g. only for new chemical entities) and by providing that reliance on the originator's safety and efficacy data is allowed in case of compulsory licensing.

Other "TRIPS-plus" Provisions

Requirements to offer exclusive rights to originator products that go beyond what is mandated by the TRIPS Agreement are sometimes referred to as "TRIPS-plus" requirements. Data exclusivity is an important example. But it is not the only example. Other "TRIPS-plus" requirements are for instance:

- *Patent term extensions*, i.e. provisions to extend the duration of a patent beyond the 20 years required by TRIPS, in order to compensate for delays in granting the patent or in registering the medicine. It is important to note that there is no obligation, from an international/legal perspective, to grant such extensions[4].
- *Limitations of the grounds for compulsory licenses*, which may preclude issuing a compulsory license for reasons of public health. Requirements to limit the grounds (or reasons) for issuing a compulsory license go directly against the Doha Declaration[5], which has unambiguously confirmed that countries are free to determine the reasons for granting compulsory licenses.
- *Linkage between patent status and generic registration*, meaning that the Regulatory Authority may not register generic versions of a pharmaceutical that is under patent. This would be problematic, since the Regulatory Authority would probably lack the resources and manpower to check the patent status of each product. Moreover, in case there is a patent, regulators may not have the expertise to assess whether the patent is valid and would be infringed[6]. As a result, it is likely that they will enforce *all* patents, even invalid ones – and thus create additional and unnecessary hurdles for generic competition[7]. "Linkage" is also problematic in view of the fact that patents are private rights; as such, they should be enforced by the right holders, not by the government.

Other "TRIPS-plus" requirements deal with the administrative procedures related to patent applications and/or the granting and revocation of patents. The common feature of all "TRIPS-plus" provisions is that they have the effect to complicate and/or delay the marketing of generics, and thereby reduce access to medicines.

Yet, while these requirements are going beyond the TRIPS Agreement –or, in other words, are not required by TRIPS– in recent years, "TRIPS-plus" requirements have at times been incorporated in bilateral or regional free trade negotiations, in bilateral investment agreements and in other international agreements and treaties. From the perspective of access to medicines, this is a worrying trend; countries should therefore be vigilant and should not 'trade away' their people's right to have access to medicines.

Box 4: Expanding data exclusivity requirements

Initially, requirements for data exclusivity focused on undisclosed data that have been submitted to regulatory authorities. However, more recently, there have been cases where such demands just referred to 'information' – which could potentially expand the scope of data exclusivity significantly by preventing regulators from relying on data that are in the public domain in order to register a generic medicine.

Conclusion

Medicines fall under two separate legal and regulatory systems: the intellectual property system and the drug regulatory system. These systems have different objectives, are administered separately and function independently. Recent efforts to integrate these two systems via data exclusivity, "linkage" or other means are likely to have negative implications for access to medicines. Thus, (developing) countries would be well advised to keep these systems separate, and to reject any and all efforts to make connections between them.

[4] Moreover, it should also be noted that at times the patent holder is responsible for those delays.

[5] Declaration on the TRIPS Agreement and Public Health, see footnote 2.

[6] For these reasons, Regulatory Agencies in the EU have so far refused to implement such "linkage" between patent status and registration of medicines.

[7] In 2002, the US Federal Trade Commission found that when generic companies initiate patent litigation, they prevail in a significant number of cases.

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CAMPAIGN FOR ACCESS TO ESSENTIAL MEDICINES

MEDECINS SANS FRONTIERES

Data exclusivity in international trade agreements: What consequences for access to medicines?

(MSF technical brief)

"Data exclusivity" is a term covering measures some governments, especially the US, are seeking to include in bilateral and regional trade agreements. The implications of such measures need to be understood, because they could have far-reaching ramifications for access to medicines.

Data exclusivity refers to a practice whereby, for a fixed period of time, drug regulatory authorities do not allow the registration files of an originator to be used to register a therapeutically equivalent generic version of that medicine. Data exclusivity is completely separate from patents. In fact, the strongest impact may be felt in a country where there is no patent for a medicine - if data exclusivity is granted this will provide a monopoly for a set period (e.g. five years).

This short briefing paper outlines the consequences of data exclusivity for access to medicines and explains why countries are not obliged to agree to it.

What kind of data are we talking about?

"Data exclusivity" refers to test and other data that a pharmaceutical company must provide to a drug regulatory authority (DRA) in order to get first-time registration for any new medicine it wishes to market in a country. This test data is necessary to demonstrate the efficacy and safety of the drug. Registration - or marketing approval - by the DRA is needed before a medicine can be marketed in a country.

When generic manufacturers later apply to register another version of an already-registered medicine, they only have to demonstrate that their product is therapeutically equivalent to the original. To fulfil the efficacy and safety requirements, the drug regulatory authority relies on the registration file of the original manufacturer.

So what kind of exclusivity is it?

In order to delay competition from generic manufacturers, multinational companies have been pushing hard to obtain exclusive rights over their test data. During this period of "data exclusivity", the DRA is not authorised to rely on information in the originator dossier to approve/register generic

versions of a medicine. This period of exclusivity may vary from five years in the US to eight years in the EU and can be found in developed countries mostly in medicines legislation. Such legislation also exists in a limited number of developing countries.

Practically, data exclusivity prevents DRAs from registering generic versions of a medicine during a limited period, unless the generic manufacturer independently carries out its own tests showing the safety and efficacy of the medicine.

What are the consequences of data exclusivity for access to generic medicines?

The biggest impact of data exclusivity is on medicines that are not patented in some countries, as a result of pre-TRIPS patent laws excluding pharmaceutical patents. This is the case of most antiretroviral medicines in Guatemala for instance[1], where generic manufacturers will now have to wait five years from the date of approval of the original medicine in Guatemala before obtaining registration of their own version of the medicine[2]. In other words, even when a medicine is not protected by any patent, multinational pharmaceutical companies are assured a minimum period of monopoly in countries that provide data exclusivity. This is clearly going beyond the TRIPS Agreement (see further below).

In other situations, where a medicine is protected by patents, data exclusivity may constitute a barrier to the use of compulsory licenses. If a generic manufacturer is granted a compulsory license to overcome the patent, it will not be able to make effective use of the license if it has to wait for the expiry of data exclusivity before it can get its generic version approved by DRA and put on the market. Therefore, countries will need to ensure that the use of compulsory licences are not restricted by data exclusivity.

Data exclusivity is a means of impeding generic competition, and maintaining artificially high prices, thereby restricting access to medicines. Moreover, it could be considered unethical to require generic manufacturers to conduct their own safety and efficacy trials with proven effective compounds. Clinical trials could expose patients to sub-optimal treatment. Proof of therapeutic equivalence should be sufficient.

What is the relationship between data exclusivity and patents?

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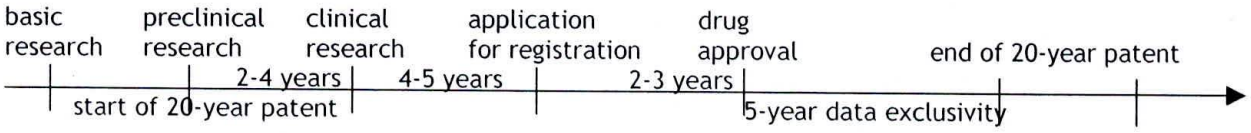
[1] This is because Guatemala only introduced patent protection for pharmaceuticals in November 2000. Consequently, all medicines which were applied for patent protection before this date cannot be patented in Guatemala (except for new improved versions that meet the patentability criteria). See MSF report *Drug patents under the spotlight - Sharing practical knowledge about pharmaceutical patents*, May 2003.

[2] In accordance with Decree 09-2003, and the recently signed Central America Free Trade Agreement (CAFTA) with the United States.

Patent application is made well before the application for drug registration, at the stage of basic research, but since patents now last for 20 years, they usually expire after the data exclusivity period.
The schematic graph below illustrates the interference of patents and data exclusivity.



Is data exclusivity another kind of intellectual property right?

Compared to more traditional intellectual property rights such as patents and copyrights, data exclusivity is very unusual since it does not require any inventive activity for it to be granted. Data exclusivity protection is instead only based on the fact that an investment has been made by the originator in carrying out the necessary tests to demonstrate the safety and efficacy of their new medicine. Although the TRIPS Agreement now requires some protection for this sort of data, it does not require that exclusive rights be granted in the same way as patents or copyright.

What does TRIPS say about test data?

Developed countries pushed very hard during the TRIPS negotiations to have data exclusivity included in the TRIPS Agreement as a new kind of IPR. They succeeded *in part*, as test data are mentioned in Section 7 of the TRIPS Agreement, but *not entirely*, as TRIPS does not talk about "exclusivity" as such.

There is only one article in the TRIPS Agreement that talks about test data: Article 39.3, which states that

> "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."

In simple words, what TRIPS says is that WTO Members should protect "undisclosed test or other data" against "unfair commercial use" and "disclosure". Nowhere does TRIPS state that countries should provide *exclusive* rights to the originator of the data for a *given* period. Rather, TRIPS simply refers generally to the need for "data protection", without answering the question of how such protection should occur.

As for other forms of IP, Article 39.3 of the TRIPS Agreement only provides a minimum international standard for the protection of the submitted

undisclosed information required for market approval of a pharmaceutical product. Since the wording of Article 39.3 is very general, Members maintain substantial flexibility when determining how submitted test data

should be protected. WTO Members do *not* have an obligation under Art. 39.3 to confer exclusive rights to test data, whether it is for three years, five years, or 10 years, as pointed out by many experts[3].

Data exclusivity is no more than "TRIPS-plus" and is designed to delay the introduction of generic competition, creating a barrier to access of medicines, in particular where there are no patent barriers.

What will be the effect of data exclusivity in bilateral and/or regional trade agreements given TRIPS flexibility?

Countries that are members of the WTO do *not* have to grant data exclusivity, as specified under TRIPS Article 39.3. However, if they agree to grant data exclusivity in a trade agreement signed after the TRIPS Agreement, they are bound by the later agreement, in accordance with the rules of international law, and will have to implement this obligation at national level.

Countries that have agreed to data exclusivity provisions in free trade agreements with the US include: Chile, Costa Rica, Dominican Republic, El Salvador, Guatemala, Honduras, Mexico, Morocco, Nicaragua and Singapore.

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3 See Carlos Correa, *Protection of Data Submitted for the Registration of Pharmaceuticals: Implementing the Standards of the TRIPS Agreement*, South Centre 2002. Available at http://www.southcentre.org/publications/pubindex.htm#books
See also the Report of the Commission on Intellectual Property Rights, *Integrating Intellectual Property Rights and Development Policy*, London, September 2002, pp.50-51 and 163.

10-July-2006

To,

Dr. Manmohan Singh,
Prime Minister of India,
South Block, Raisina Hill,
New Delhi, India-110 011.
Fax: 91-11-23019545 / 91-11-230168

Re: **Proposed amendments to the Drugs and Cosmetics Act, 1940**
and
Re: **'Data Exclusivity'**

Dear Prime Minister,

We, the Affordable Medicines and Treatment Campaign (AMTC), a national campaign aimed at creating an environment that will ensure sustained accessibility and affordability of medicines and treatment for every individual in India, write to express our grave concerns over the proposed amendments to the Drugs and Cosmetics Act, 1940 (the DCA) to introduce 'data exclusivity' that are currently being discussed by the government.

The Common Minimum Programme of the UPA government has committed to the people of India that:

> *"**The UPA Government will take all steps to ensure availability of life-saving drugs at reasonable prices**. Special attention will be paid to the poorer sections in the matter of healthcare."*

However, the proposed amendment of the DCA to introduce data exclusivity would have the opposite effect. The introduction of data exclusivity will seriously compromise accessibility and availability of essential medicines, one of the primary components of Right to Health. **We strongly feel that the introduction of such a provision is unnecessary under India's existing international obligations, and would come directly at the cost of the health of millions of India's poorest and most needy.**

Data exclusivity measures are likely to have the following impact on the right to health:

- ***Prevents the drug regulatory authorities themselves from relying on test data already in their possession for subsequent approval of generic versions of the medicine;***

- ***Data exclusivity impedes the use of compulsory licenses. A compulsory license is granted to a generic manufacturer by the government to overcome a patent monopoly to increase access to the medicine. However the generic manufacturer***

will not be able to make use of the license to manufacture and sell the medicine if it is unable to obtain marketing approval without first generating test data;

- ***Unpatentable or Off-patent drugs will get protection without any beneficial contribution to the society.***

- ***Effective competition in the market would be prevented resulting in higher prices for the drugs.***

- ***Theoretically it does not legally prevent generic manufacturers from generating their own test data for marketing approval. However in reality the financial resources and the time needed for conducting clinical trials for generating test data already available with the Drug Controller creates a market barrier that is difficult for generic manufacturers to overcome;***

TRIPs Does Not Require Data Exclusivity.

The move to amend the DCA to provide data exclusivity is apparently linked to India's obligations under Article 39.3 of the TRIPS Agreement. Article 39.3, however, only requires countries to protect *undisclosed test* or other *data* relating to new chemical entities against *unfair commercial use.* **In fact, "data exclusivity" was *specifically* excluded from the language of Article 39.3 during the TRIPS negotiations.**

Under the current drug registration process, a generic company does not have access to and never uses the originator's data. Thus, there is no unfair commercial use by the generic companies. On the other hand the regulatory authorities may rely on such data, but since the regulating authority is not a commercial organization, this is not 'commercial use' as per TRIPS.

In the context of Article 39 of TRIPS, the phrase 'commercial use' is used in relation to unfair trade practices, which cannot cover the work of a government body entrusted with the task of protecting the public. Thus, it is entirely consistent with the language of Art. 39.3 to simply require that data submitted for drug approval is protected from 'unfair commercial use' by the office of the Drug Controller while allowing the Drug Controller to rely on this data to approve subsequent generic applications. Indeed, the World Health Organisation concludes that TRIPS does not require data exclusivity, and states that "from the perspective of public health and access to medicines, it is preferable not to grant data exclusivity."

The impact of Data Exclusivity on Access to Medicines

With the passage of the Patents (Amendment) Act, 2005, Parliament attempted to find a delicate balance between the need to comply with India's international obligations and the need to ensure that monopolies are not granted at the cost of public health. The introduction of a data exclusivity provision would upset this delicate balance in favour of the multinational pharmaceutical industry and at the cost of the people of India. Special provisions that Parliament introduced to ensure that frivolous patents are not granted, as well as provisions designed to ensure the ready availability of essential medicines in the

event of public health crises could be weakened or made ineffective with the introduction of a data exclusivity provision.

Unpatented medicines / Patent expired medicines

More importantly a data exclusivity provision will prevent competitors from registering generic versions of medicines even when there is no patent covering a drug. India's Patents Act contains some unique provisions that were introduced in order to prevent the patenting of frivolous improvements to already-existing drugs that only serve to extend the patent holder's market dominance. Because of such provisions, it is likely that many drugs that have been granted patents in other countries will not be patent protected in India, and for good reason. However, with a data exclusivity provision, a drug manufacturer would nevertheless have an opportunity to enjoy a period of monopoly over a drug that has been denied a patent. This is not only contrary to Parliament's intent in enacting special protections within the Patents (Amendment) Act, but completely against the liberalization policy India adopted since 1992 by preventing effective competition and price reduction. This would seriously affect the accessibility and affordability of medicines.

Compulsory license

Data exclusivity could prevent registration of medicines produced under a compulsory license if any compulsory license is issued in public interest. Even if companies are given compulsory licenses to produce medicines when a serious health crisis occurs they could be prevented from relying on the data for registration and delay the entry into the market. This would make the compulsory license provisions useless and there would not be any mechanism to combat such situations.

Preventing competition

If a data exclusivity provision is enacted, then generic competitors have only two options. Either to wait till the data exclusivity period is over and then rely on the data of the originator and get marketing approval for their generic drug or to produce the relevant data by conducting their own clinical trials and then get registration. Given the costs and time required for clinical trials most companies may prefer the first option which would delay the entry of competitors in the market thereby maintaining higher prices for a longer time.

Higher costs for drugs

If at all a generic company decides to conduct its own clinical trials and produce the data to enter the market earlier the consequent prices of the dugs will be higher and affect the accessibility and affordability of the drugs for the poor classes in India.

Ethical issues

Data exclusivity also brings to light many ethical issues which for a country like India has very serious consequences. Prevention of relying on the originator's data would compel competitors to conduct their own clinical trials. This is clearly duplication of clinical trials solely for commercial purposes, i.e. ostensibly for protecting the investment of a company in originating data for drug registration. This kind of protection is ethically

unjustifiable. Data exclusivity is not intended to be an incentive for data generation because data generation is not a creative activity, which is presumed to be generated only through incentives. It is a mandatory requirement to ensure the safety and efficacy of the drugs to protect the public interest. Moreover additional clinical trials would increase the price of the concerned drugs. It would make the drugs inaccessible and unaffordable to majority of the people in India. Furthermore when a drug already has been proven to be safe and effective, it is not justifiable to test the drugs again on humans simply to reproduce data to prevent relying the originator's data.

India is a signatory to the Doha Declaration on the TRIPS Agreement and Public Health, which states, in part, "**we affirm that the [TRIPS] Agreement can and should 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**." This principle was recently reaffirmed and reiterated at the UNGASS review meeting in May 2006, in part through the active participation of the Indian delegation. This is in keeping with the guarantee of the right to life and health under Article 21 of the Constitution of India. The introduction of a data exclusivity provision is both unnecessary under TRIPS and harmful to public health, and would be nothing less than a betrayal of the solemn promise of Doha.

Considering India's international obligations and India's internal needs, a data exclusivity provision is not required in any way. The need of the time is to have a clear policy that facilitates access and affordability of drugs thereby fulfilling the right to health of the people of India. We hope these issues will be taken up strongly and will be given serious consideration in any changes intended to be made now or in the future in the policies or in the legislations.

Regards,

For the Affordable Medicines and Treatment Campaign

cc:

B.P Sharma
Joint Secretary
Dept. of Health
Ministry of Health and Family Welfare
New Delhi
Fax: 23061723

Mr. Prasanna Hota
Secretary
Dept. of Health & Family Welfare
Ministry of Health and Family Welfare

Government of India
Nirman Bhawan, New Delhi 110011
Tel: 23061863/23063221
Fax: 23061252

Mr. Gurdial Singh Sandhu
Joint Secretary (Pharmaceuticals Industry) & Chief Vigilance
Officer, Department of Chemicals & Petrochemicals
Room No.340-B A wing, Shastri Bhawan,
Dr. Rajendra Prasad Road,
New Delhi 110 001
Phone: 23385131,
Fax: 23387222

Mrs. Satwant Reddy
Secretary
Department of Chemicals & Petrochemicals
Ministry of Chemicals and Fertilizers
Room 501 'A' Wing, Shashtri Bhawan
New Delhi 110 001
Ph: 23382467, Fax: 23387892

Sri Kamal Nath
Honourable Minster of Commerce & Industry
Room No. 45, Udyog Bhavan
New Delhi
Tel: 23061008, Fax: 23012947

Sri Ramvilas Paswan
Honourable Minister of Chemicals and Fertilizers
Shastri Bhawan, Dr. Rajendra Prasad Road
New Delhi 110 001
Tel: 23386519, Fax: 23384020

Dr Anbumani Ramadoss
Honourable Minster of Health and Family Welfare
Nirman Bhavan, Maulana Azad Road
New Delhi 110011
Tel: 23061751, Fax: 23062358

Mrs. Sonia Gandhi
President
Indian National Congress Party

PM urged not to introduce data exclusivity

Repealing clinical trials will force drug companies to perform unethical studies

NEW DELHI: The Washington-based non-profit agency, Global AIDS Alliance, has urged Prime Minister Manmohan Singh to ensure that amendments are not made to the Indian Drugs and Cosmetics Act to introduce data exclusivity provisions as this will seriously affect India's ability to provide generic drugs to millions of people in developing countries.

In a letter sent to Dr. Singh, the Alliance has expressed concern that such amendments will have adverse effects on the global availability of affordable essential medicines meant to treat HIV/AIDS, hypertension, diabetes, asthma and many other diseases. "Without Indian generic drugs, millions of people in developing countries will die as a result of lack of access to affordable medicines," it says.

The broad based alliance, which has Bishop Desmond Tutu on its board of directors, argues that data exclusivity provisions, if added to the Drugs and Cosmetic Act, will prevent generic companies from using data on existing drugs to gain regulatory approval for generic versions. It maintains that generic companies will be forced to repeat time-consuming and expensive studies to receive regulatory approval.

Essential medications will be prohibitively expensive without the competition from generic companies and generic drugs will take years to bring to market under data exclusivity laws, it has stressed.

The Alliance has stated in the letter that repeating clinical trials will force drug companies to perform unethical studies that withhold medicines known to be effective from the control group. "The people of India and the developing world will be denied access to the newest treatments available to those who can afford brand name drugs," it has said.

In addition, it has pointed out that the TRIPS agreement does not require India to implement data exclusivity provisions. Article 39.3 simply requires that members protect "undisclosed test or other data... against unfair commercial use."

It notes that World Health Organization's Commission on Intellectual Property Rights, Innovation, and Public Health recently reinforced the view that TRIPS does not require data exclusivity.

Underlining the need to avoid amending the Drugs and Cosmetics Act, the alliance says the Commerce Ministry of Commerce has already publicly stated its opposition to the implementation of data exclusivity provisions.

"We hope that the Ministry of Health and Family Welfare and the Ministry of Chemicals and Fertilizers will follow suit and oppose a data exclusivity amendment to the Drug and Cosmetic Act," it says.

http://www.hindu.com/2006/06/25/stories/2006062502211300.htm

Pesticide MNCs seek 5-10 year `data exclusivity'

Harish Damodaran New Delhi , March 7

MULTINATIONAL crop protection chemical majors are lobbying hard for a 5-10 year period protection or `exclusivity' on the test data relating to new pesticide molecules, which they are now obliged to submit to the Government to obtain authorisation for marketing in the country.

The demand — aimed at tackling `unfair' competition from domestic `me-too' generic agro-chemical manufacturers — is broadly in line with what their counterparts in the drugs/pharma industry have been seeking.

Currently, Section 9 (3) of the Insecticides Act, 1968 mandates any manufacturer or importer wanting to introduce a new pesticide to obtain approval from a Registration Committee under the Agriculture Ministry. The registrant, in turn, has to furnish detailed information (typically running to 20,000 or more pages) pertaining to the chemistry, toxicology, bio-efficacy and maximum residue limits (MRL) of the proposed molecule, which also covers the data generated during field trials here.

The Committee, "after satisfying itself that the insecticide conforms to the claims made by the importer or by the manufacturer", then issues a registration certificate.

As of now, there are 184 pesticides registered for use in the country, the bulk of which are proprietary molecules of multinationals, for which they were also the original Section 9 (3) registrants here. These include the more recent, `new generation' molecules touted to be relatively environment-friendly, by virtue of requiring lesser number of sprays for producing the same impact.

While the original registrant has to provide detailed test data to the authorities, there is no such stringent binding, however, on subsequent `me-too' registrants desiring to import or manufacture the same pesticide under Section 9 (4) of the Act. Section 9 (4) registrants seeking to manufacture formulations of the already registered molecules do not have to submit any data.

Even with regard to the technical material, the `me-too' applicant has to only demonstrate the similarity of the molecular structure of his pesticide with the original molecule. "In addition, he has to submit minimal bio-efficacy and toxicological data, which runs to a few hundred pages, at the most", claimed an official of a leading agro-chemical MNC affiliate.

As a result, for almost every molecule originally registered by an MNC here, there are several `me-too' manufacturers today. Take Imidacloprid, an insecticide for seed treatment and foliar application, registered in 1999 by Bayer India.

This molecule is now produced by a host of domestic companies, including Rallis India Ltd, Nagarjuna Agrichem Ltd, Sudarshan Chemical Industries, Excel Industries, Jaysynth Dyechem Ltd, Bhagirdha Chemicals and Bhaskar Agro Chemicals Ltd, who have all been granted registration for technical indigenous manufacture under Section 9 (4).

The same is true for Sulfosulfuron, a wheat herbicide that Monsanto launched in the 1998-99 rabi season under the `Leader' brand. Today, the list of `me-too' manufacturers of this molecule include United Phosphorous, Nagarjuna, Gharda Chemicals and Atul Ltd. Atul has similarly received the nod to indigenously manufacture Metsulfuron methyl, for which E.I. Dupont India was the original Section 9 (3) registrant.

Acetamiprid — an insecticide sprayed against sucking pests in cotton and originally registered by De-Nocil, a Dow Chemicals subsidiary — is now also manufactured by Rallis and Gharda Chemicals.

The MNCs contend that the absence of protection for the voluminous test data that they are statutorily obliged to submit to the registration authorities for their pesticides "allows other companies to access this information and come out with the same or similar molecules".

Moreover, since the `me-too' registrants do not have to incur the costs involved in developing the molecule and generating the detailed field trial data, they are able to reverse engineer and market the same pesticide at much lower prices.

"What we want is a 5-10 year period of data exclusivity during which the Government respects the confidentiality of the test data furnished by any agro-chemical company for a particular molecule.

Over this period, applicable from the day of according registration, this data cannot be referred to by another company. Besides, we are seeking a minimum time gap for granting me-too registration for any pesticide, subsequent to its original registration under Section 9 (3). This interval will help us recover the cost of R&D and data generation", the official added.

What the WTO agreement says

Article 39.3 of the World Trade Organisation's (WTO) Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS), to which India is a signatory, provides that "members, when requiring as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilise 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".

While member-countries are obliged to provide data exclusivity to protect against "unfair commercial use", the Article does not, however, explicitly stipulate any specific period for such exclusivity to ensure that "undisclosed test data" is not misappropriated. This is unlike the 20-year protection period given in respect of product patents from the date of filing and to extend to all products, for which patents were filed after January 1, 1995. The country is also required to formally institute a product patent regime from January 1, 2005.

If the Government were to accept the demand for granting a 5-10 year period of data exclusivity, over and above the mandatory 20-year protection on patents, it would mean going beyond even TRIPS and inviting allegations of "sell-off to the global pharma and agro-chemical lobby". It is precisely for this reason that the Commerce Ministry, which, only last year, said to be favourably inclined to a 3-5 year data exclusivity period, has suddenly developed cold feet and passed on the buck to the administrative ministries concerned — Agriculture and the Department of Chemicals 1& Petrochemicals.

Opponents of data exclusivity say that the granting of product patents provides sufficient protection against `me-too' generic producers, who will, from next year onwards, not be able to manufacture any drug or pesticide that has been patented after January 1, 1995.

It is a different matter though that most of the `new generation' pesticides introduced by multinationals in the country in the last 4-5 years pertain to molecules that were patented prior to 1995. The gap between the filing of patent for a product and for its actual introduction in the marketplace is usually in the region of 8-10 years. Providing data exclusivity would, in a sense, extend protection to any newly introduced pesticide, irrespective of whether or not it enjoys patent rights.

http://www.thehindubusinessline.com/2004/03/08/stories/2004030800560700.htm

PATENTS & DATA EXCLUSIVITY

Wednesday, September 10, 2003 08:00 IST

P A Francis

After successfully managing the WTO agreement on TRIPs and Public Health in its favour, the US and its powerful drug multinationals are actively pursuing for a data exclusivity provision for drugs in the Indian regulatory system. A handful of top Indian drug companies are also backing this US move, of late. The goal is to convince or force the Indian government to incorporate data exclusivity condition at least into the new patent law of the country expected in place by 2005, if not early. In the US, data exclusivity is given for five years whereas in Europe it is anything between 6 to 10 years.

The research-based US and European pharma companies feel that India should guarantee to a period in which test and clinical data of a new drug filed with regulatory authorities should not be referred to by any other company for obtaining marketing authorization to launch a similar product. Currently, when manufacturers of generics apply for approval of their drug, they claim bioequivalence to the originator's product without conducting clinical trials by themselves. They just make a reference to the originator's submitted data for approval. Regulatory authorities then rely on such data for determining the safety and efficacy of the drug before marketing approval is granted to subsequent applicants. Such a position is justified considering the social and economic costs involved in the repetitive animal and human trials in developing countries. What the MNCs fear is that the generic companies, which usually wait to launch a copycat product soon after the drug goes off patent, may capture their market by using the inventor's clinical data. It is possible that entry of generics would take away a good part of the drug's market because of the lower prices. But on the other hand, data exclusivity will provide a free hand to the originator company to continue with its monopoly pricing for an undesirably longer period. For instance, if five-year data exclusivity is granted in any country, the original inventor could get a market exclusivity for 23 years if the product is introduced in that country in the 18th year of the patent life. Therefore, it is important that if at all India decides to allow data exclusivity provision, that should run concurrently with the expiry of patent. The stand of the US based Pharmaceutical Research and Manufacturers of America that protecting confidentiality of clinical data submitted to the regulators is a an obligation under the Article 39.3 of the TRIPs agreement does not seem to be based on a correct understanding of the provision.

http://www.pharmabiz.com/article/detnews.asp?articleid=17925&sectionid=47

Data Exclusivity and Market Protection

Data Exclusivity guarantees additional market protection for originator pharmaceuticals by preventing health authorities from accepting applications for generic medicines during the period of exclusivity ...

What is data exclusivity?

Data exclusivity guarantees additional market protection for originator pharmaceuticals by preventing health authorities from accepting applications for generic medicines during the period of exclusivity.

The effective period of ***market exclusivity*** gained by the originator company is the period of data exclusivity (currently 6 or 10 years) plus the time it takes to register and market the generic medicine — a further 1 to 3 years.

Data Exclusivity was introduced in 1987 to compensate for insufficient product patent protection in some countries. However, strong product patents are now available in all 25 EU Member States. The rules on data exclusivity have been changed in the new EU pharmaceutical laws adopted in 2004.

Generics do not use originator data

Data exclusivity prevents regulatory authorities from assessing the safety and efficacy profile of a generic application for a period of time beginning from the first marketing approval of the originator product. Generics applications do not use data from the originator registration file. They are approved on their own merits, using their own development data, under the same EU requirements as the originators. The originator's data is never released to third parties by the medicines authorities. It therefore is not and cannot be used by generics producers.

However, since generics contain well-known, safe and effective quality substances, unnecessary animal testing and clinical trials on humans performed by the originators are not repeated. Instead, regulatory authorities evaluate the generic application against the originator documentation on file — but only after the period of data exclusivity has expired. This assessment is carried out internally by the authorities. In no instance is the originator's research data released or disclosed to the generics producer or anyone. The generics manufacturer never sees the originator data.

Data Exclusivity is not Data Protection

Data exclusivity has nothing to do with protecting research data. Long after the data exclusivity period has expired, the originator documentation remains protected by copyright laws and other legal provisions. Data exclusivity merely extends the originator company's market monopoly over a product by not allowing the authorities to process an application for marketing authorisation.

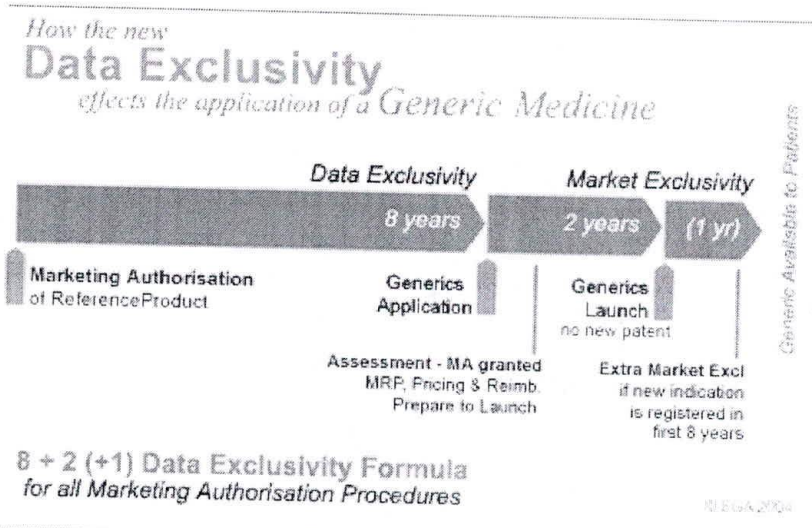
Current legal framework

Under Directive 2001/83/EC, EU data exclusivity laws guarantee market protection for originator medicines for either 6 or 10 years. Data exclusivity extends for six-years after European marketing authorisation is granted in Austria, Denmark, Finland, Greece, Ireland, Portugal, Spain, Norway and Iceland and is the period adopted by the 10 new Member States during their negotiations for EU accession. Ten-year periods of exclusivity are operated in Belgium, Germany, France, Italy, Luxembourg, the Netherlands, Sweden and the UK. A ten-year period is also granted to an originator gaining marketing approval through the Centralised Procedure.

New legal framework - Harmonisation of the data exclusivity period and addition of new periods of data exclusivity

The New EU Pharmaceutical Legislation adopted in 2004 has created a harmonised EU eight-year data exclusivity provision with an additional two-year market exclusivity provision. This effective 10-year market exclusivity can be extended by an additional one year maximum if, during the first eight years of those ten years, the marketing authorisation holder obtains an authorisation for one or more new therapeutic indications which, during the scientific evaluation prior to their authorisation, are held to bring a significant clinical benefit in comparison with existing therapies. This so called 8+2+1 formula applies to new chemical entities (NCE)s in all procedures and to all Member States (unless certain new Member States are awarded derogations, which they can request following publication of the new law).

In practical terms, this means that a generic application for marketing authorisation can be submitted after Year 8, but that the product cannot be marketed until after Year 10 — or 11 (see chart below).



The revised legislation also provides a one-year data exclusivity provision for products switching from "prescription-only" to "over the counter" (OTC) status, on the basis of new pre-clinical or clinical data. The law also grants one-year data exclusivity for any new indication for a product which can demonstrate well-established use. This latter provision is non-cumulative ie, it covers only the use of the new indication, and can only be used once.

Because of the adamant opposition to this overall increase in data exclusivity from the current six-year countries — especially from the Accession countries, who had not agreed to this law in their accession agreements, were not yet entitled to vote on it during the legislative process, and who felt it would have a significant effect on their government medicines bill — an additional clause was inserted at the last minute making the law prospective. As a result, the new periods of data exclusivity will only take effect for reference products applying for marketing authorisation after the new law is fully in effect (around November 2005). Therefore, the first generics applications under the 8+2+1-year data exclusivity period will not occur until late 2013.

http://www.egagenerics.com/gen-dataex.htm

Centre mulls law change: Firm should test before selling drug
Toufiq Rashid

NEW DELHI, JUNE 21: As A follow-up to the TRIPS agreement on intellectual property rights, the Centre is now thinking of amending the Drug and Cosmetics Act to make it mandatory for generic companies in India to conduct their own clinical trials before marketing a drug.

The amendment will also provide data exclusivity to the original producer of the drug for about five years, meaning it will take that much time for cheaper versions of the drug to hit the market. The various ministries concerned — Health, Commerce, Chemicals and Fertilisers, Science and Technology — however, differ on the need for the amendment. The PMO has called a meeting of the ministries and the Centre for Scientific and Industrial Research on July 12, 2006.
According to the existing law, a pharmaceutical company provides test data for safety and efficacy to the drug regulatory authority to get first-time approval or registration for a new medicine before marketing it. For drugs already registered in other countries, the Drug Controller in India relies on the data already submitted to their counterparts for approval in other countries such as the US, UK or Europe.
The generic manufacturers in India only need to provide a 'bio-equivalence certificate' to prove that the drug produced by them is equivalent to the original. The amendment in the existing law would mean that generic manufacturers have to conduct their own tests before seeking approval for marketting the drugs in India. The data exclusivity is not likely to be restricted to patented drugs but new use or innovation of old drugs as well.
The Ministry of Health is opposing the amendment as it believes the cost of treatment will go up. ''We are not against innovation or foreign investment but have to find some middle path and not go for extremes,'' said Secretary (Health) PK Hota.
Generic drug manufacturers have already made representations to the expert group against an amendment. ''Various submissions have been made to the expert group that India need not go beyond what is in the TRIPS agreement. Our immediate obligation is to complete the TRIPS agreement so that data is protected against unfair commercial use and not made available to competitors,'' said DG Shah, secretary-general of the Indian Pharmaceutical Alliance. ''This provision will create monopolies in the market which will lead to increase in the prices of the medicines as generic companies cannot cover the cost of clinical research. Even if they do, the research will take years and the generic versions will come late into the markets.''
Those in favour of the amendment say it will help rid Indian companies remove of the copycat tag. ''Indian companies are feeling unsafe to submit clinical data as it is passed to rivals in the market. So we need to feel safe to do drug trials in the country. Besides, it will encourage multinationals to do research in diseases affecting the country, which has not been happening in the past,'' said Harinder Sikka, president of corporate relations at Nicholas Piramal.

toufiq.rashid@expressindia.com
http://www.indianexpress.com/story/7172.html

Elusive data exclusivity norms

India should learn from the competition

BJP leader Murli Manohar Joshi's letter to the Prime Minister cautioning against allowing for data exclusivity once again brings to the fore the reluctance to concede on intellectual property rights (IPR) issues, even after other countries have taken a clear stand long before. Data exclusivity provisions of the Trade Related Intellectual Property (TRIPS) agreement, requires WTO member-states to protect clinical data filed for securing marketing approval or for registration. It means that the clinical data filed by patent holders should not be used for ensuing applications on similar products. This is because clinical tests for generating data are very expensive—as much as $500 million or even more—and it would be only fair to the original innovators if competing products are not allowed to benefit from the data, at least for a specific period of time.

Opponents of data exclusivity provisions argue the TRIPS provisions speak only about the protection of test data against unfair use and nothing on data exclusivity. It is also pointed out that data exclusivity might restrict access to drugs, especially generics, which helps keep down prices. Other arguments focus on unwarranted extension of patent rights and obstacles to compulsory licensing, which helps poor countries to avert emergencies. The World Health Organisation (WHO) support to the views that IPRs and drug regulations are separate issues, also buttress the opposition claim. But almost all developed countries and most developing ones, including China, Brazil and South Africa, to name a few, have ruled in favour of data exclusivity. The extent of non-conformity across nations is mainly about the period of exclusivity: it is seven years in the United States and six years in China. The EU allows member-countries a six or 10-year period, depending on product characteristics. Even Israel, one of the most important producers of generic medicines, gave in to demands for data exclusivity around last year.

Countries have little choice, as the potential losses from not having data exclusivity are much higher. How will it be in India's interest if the absence of these norms discourages companies from introducing new products? Strong IPRs remain a keystone to accelerated growth of the buoyant Indian pharmaceutical industry. And it certainly would not be in India's interest if the R&D majors take fright and decide to pull out their investments. So, it is time we took the call and sent the right signals. Any further delay will only benefit the competition.

Posted online: Friday, June 23, 2006 at 0000 hours IST

http://www.financialexpress.com/fe_full_story.php?content_id=131450

Joshi cautions govt on data exclusivity

SEBASTIAN PT

Posted online: Saturday, June 17, 2006 at 0000 hours IST

NEW DELHI, JUNE 16: Stating that certain ministries were on the verge of conceding to MNCs' demand of data exclusivity, BJP leader Murli Manohar Joshi on Friday cautioned Prime Minister Manmohan Singh on ministries pushing for 'TRIPS-plus' measures for legislation. In a letter to the Prime Minister on Friday, Dr Joshi said the demand for data exclusivity had been raised at a bilateral level with the Indian government by MNCs and the US government.

It is understood that the ministries concerned have been deliberating on this issue for the last two to three years and now the government is on the verge of conceding to the bilateral demand of data exclusivity, instead of implementing data protection as stipulated in the Trade Related Intellectual Property Rights (TRIPS agreement)," he said.

He said that conceding to the demand for data exclusivity would have serious implications for the role of domestic enterprises in the fields of pharmaceutical and agro-chemical products. Besides, even if the domestic firms have been granted compulsory licence to use the patented subject matter they would be prevented from taking marketing approval during the period the data exclusivity is in operation.

Thus, the compulsory licence provision, a TRIPS-compliant provision available with national governments to sidestep patents in the event of a national emergency, would be rendered unimplementable, he said. This would give the patent holder an unfair advantage, he argued.

Attaching a copy of World Health Organisation (WHO) document, the former minister said that even the WHO has recommended that the developing countries would be well advised to keep the two systems of IPR and drug regulation separate, and to reject any and all efforts to make connections between them.

Protection Matters

- Data exclusivity will have serious implications in the areas of pharmaceuticals and agro-chemical products
- Even the WHO document stated that TRIPS required data protection
- National laws do not need to be more stringent or more restrictive than TRIPS

The WHO document further stated that TRIPS requires data protection, but not data exclusivity - and national laws do not need to be more stringent or more restrictive than TRIPS. In fact, the commerce ministry, which was represented in a high-level committee which deliberated on the issue, had clearly stated that data exclusivity is no TRIPS obligation. Data protection merely mandates the regulators concerned to not publish the invention-related data submitted before them for regulatory approval. Data exclusivity, on the other hand, prevents them from even using such data for subsequent applications. In the pharma industry, for instance, this would result in unnecessary burden on the second and subsequent applicants in terms of regulatory procedures such as clinical trials.

Dr Joshi, who is also the chairman of the parliamentary standing committee on commerce, said that the data exclusivity issue and its implications were also brought before the panel in a meeting held recently. "In my opinion, the views of the WHO deserve an indepth consideration," he insisted. He pointed out that the Uruguay round of GATT negotiations had rejected the demand by the US and other developed countries for data protection/ exclusivity. "Only specific provisions was incorporated in Section 7 of the TRIPS pact for protection of undisclosed information," he said.

http://www.financialexpress.com/fe_full_story.php?content_id=130840

Erroneous exclusivity

AMIT SEN GUPTA

Posted online: Friday, June 23, 2006 at 0000 hours IST

The government had recently set up an inter-ministerial group to opine on the issue of data exclusivity (DE) and it is understood the PMO has convened a meeting in July to arrive at a final position.

DE refers to a practice whereby, for a fixed period (usually five years), drug regulatory authorities do not allow the data filed by the originator company to get marketing approval to be used to register a generic version of the same medicine. Many assume that if national laws allow for patent protection, they also need to allow for DE. Incorrect on several grounds. Patents and DE are entirely different concepts. In fact, enforcement of DE can have the biggest impact in situations when patents cannot or are not being enforced. Second, the TRIPS Agreement does not mention DE, but 'Data Protection.' Prominent intellectual property experts have said if regulatory agencies do not share the data with other companies or make it public, the requirements under TRIPS are met. This does not prevent regulatory agencies from registering generic drugs if the innovator firm's drug has already been approved. Thus, in India's case, very little needs to be done—possibly a small insertion in the Drugs and Cosmetics Act, clarifying that test data from an innovator company will not be made public or shared with its competitors for a fixed period.

Under the guise of DE, drug regulatory authorities are being asked to reject the application for marketing of a drug by a local company if it doesn't submit fresh data from its own clinical trials. If the same agency has approved a drug based on clinical data provided by one company, there is no logical reason why the same drug should be refused marketing approval if another company produces it, as the issues of safety and efficacy have already been taken care of when the originator company's drug got approval.

For India, the principal instrument to curb the monopoly of MNCs is the use of a compulsory licence. But if India allows for DE, such a licence would be useless, as the DGCI would then insist Indian firms conduct fresh clinical trials before getting marketing approval. Such trials are expensive and would add to the cost of the drug, and being time-consuming, delay its introduction. If we know a drug is useful and safe, to conduct trials again on humans is unethical.

There are clear reasons why India need not allow for DE. It is not required under TRIPS. It is unfortunate the government should seriously consider amending domestic laws under foreign commercial pressure. To allow for DE, the Drugs and Cosmetics Act has to be amended. Parliament should reject it.

—The writer is general secretary, All India Peoples Science Network, Delhi

'Life-saving drugs to be out of reach of India'

REUTERS

Posted online: Friday, June 23, 2006 at 1210 hours IST

NEW DELHI, JUNE 23: Plans to change India's drug approval system would price life-saving drugs out of reach of millions of poor people by preventing generic versions being made, campaigners said on Thursday.

New Delhi, under pressure from the United States and global drug giants, is considering a law that could effectively grant a monopoly to the developer of a new drug for several years even without a patent.

"This will seriously affect accessibility to essential drugs for people in developing countries," said Leena Menghaney of Swiss-based Medecins Sans Frontieres, which has been campaigning for better access to healthcare.

The law would particularly affect people with HIV who had developed immunity to first-line anti-retroviral drugs and were waiting for second-line drugs to become affordable, she added.

Making generic copies of a new, unpatented drug is a hugely lucrative business in India.

Once a new drug is approved for sale, other drug companies only need to point to the clinical safety data already filed with India's drug controller by the drug's original developer, and prove that their generic drug is identical to the original.

But innovating drug companies -- which invest millions of dollars collecting the necessary data they need for marketing approval through clinical trials -- say this is unfair.

This system allows them to recover little of their investment and reduces the incentive to research and develop new drugs, they say.

India, as a member of the World Trade Organisation, should give them exclusive rights to reap the benefit of their data for several years under the Trade-related aspects of Intellectual Property Rights (TRIPS) treaty.

In bilateral talks with New Delhi, Washington is also urging India to adopt the change.

But others, including the World Health Organisation, say data exclusivity goes beyond what TRIPS requires and should not be introduced at the expense of public health.

They say generic drug companies are unlikely to invest in conducting their own trials and would have to wait for the data exclusivity period to end before making their cheaper versions.

Indian officials said the government was considering a safeguard in the new law that would allow it to override data exclusivity in the interest of Indian public health. The possibility of generic drug-makers paying royalties to use other companies' data was also being looked at. "We are still trying to evolve some kind of consensus," Gurdyal Sandhu, a top official in the Ministry of Chemicals and Fertilisers, told Reuters.

http://www.financialexpress.com/latest_full_story.php?content_id=131553

India law could hit access to vital drugs - activists

Plans to change India's drug approval system would price life-saving drugs out of the reach of millions of poor people by preventing generic versions being made, according to campaigners on Thursday, reports Reuters.

New Delhi, under pressure from the United States and global drug giants, is considering a law that could effectively grant a monopoly to the developer of a new drug for several years even without a patent. "This will seriously affect accessibility to essential drugs for people in developing countries," said Leena Menghaney of Swiss-based Medecins Sans Frontieres, which has been campaigning for better access to healthcare.

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http://news.moneycontrol.com/india/news/topindianews/indialawcouldhitaccesstovitaldrugsactivists/resultsviewsipomfinsurancetaxnriinterviewsceocommentspressreleases/market/stocks/article/19146/999999

& Member of Parliament
10, Janpath
New Delhi 110 001
Tel: 23014161, 23012656

Sl.No. ಕ್ರ.ಸಂ.	Name. ಹೆಸರು	Organization/Place. ಸ್ಥಳ / ಸಂಸ್ಥೆ	Signature ಸಹಿ
1	Jyothi Kiran	MILANA	Jyothi
2.	Soubhagya S.	ActionAid International	Soubhagya
3.	Christy Abraham	~~Oxfam~~ ActionAid International India	Christy
4.	Manjula	Arundhaya Network	
5.	Kailash	Arunodaya Network	
6.	K.S. Nandish	Chiraseevana Networks Tumkur (P.L.W.H.A)	K.S. Nandish
7	[illegible]	VMS	Rosi
8	[illegible]	VMS	[illegible]
9	[illegible]	VMS	
10	Shanthar.	K.N.P+	Shantha
11.	M. Anusuya	MILANA	M. Anusuya
12	D. R. Chandra Shekar	K.N.P+	21/07/06
13.	NEELAMMA	MILANA.	
14.	RENUKA	MILANA	Renuka
15	Pushpa.	[illegible]	

P. Saroja

Malathi

Chandrika

K. Anuradha

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Ref:

July 25, 2006

Shri. Sathya Murthy
The City Editor
The Hindu
Bangalore
Fax: 22864052

SUB: CIVIL SOCIETY GROUPS IN KARNATAKA DENOUNCE DATA EXCLUSIVITY – DEMAND ITS IMMEDATE REJECTION

Dear Shri. Sathya Murthy,

The civil society in Karnataka, including health groups, lawyers' groups, and civil society organizations working on HIV/ AIDS and other health and development issues (list of persons and organisations attached) have strongly protested against the inclusion of 'data exclusivity' by amending the Drug and Cosmetics Act. They have warned of the disastrous consequences that such a move will have on the cost of generic drugs and the costs of health care which will greatly impact people's access to medicines.

A letter to this effect was sent to the PM and other ministries (including Chemicals & Fertilizers, and Health & Family Welfare). We request you to cover it in your esteemed publication. The letter to the PM along with the list of organisations / networks who have called for the rejection of data exclusivity is enclosed.

Thank you.

Sincerely,

Naveen Thomas
Health Policy Fellow
Community Health Cell

Ref: CHC/ /2006/

August 8, 2006

To

Shri Ram Chander
Under Secretary to the Govt. of India
Ministry of Chemicals and Fertilizers
Department of Chemicals and Petrochemicals
Shastri Bhawan, Dr. Rajendra Prasad Road
New Delhi 110 001
Ph: 011-23384086

Dear Shri Ram Chander,

Sub: More information regarding the impact of data exclusivity on people's health
Ref: Your letter dated 28 July 2006

Thank you for your response to our letter expressing concern about data exclusivity and its impact on people's health. I am enclosing the relevant sections of the The Report of the Commission on Intellectual Property Rights, Innovation and Public Health (CIPRIPH) for your reference. The whole report can be downloaded from the following link:
http://www.who.int/intellectualproperty/en/
Alternatively, you could write to World Health Organization, Regional Office for South-East Asia, World Health House, Indraprastha Estate, Mahatma Gandhi Marg, New Delhi 110 002, Ph: 23370804, 23370809-11, Fax: 23370197, 23379395, 23379507 for a copy.

For additional information, I am enclosing Medecins Sans Frontieres (MSF)'s briefing note on data exclusivity. As you know, MSF is a Nobel Peace Prize winner and is well known for its work on access to medicines. I am also enclosing a recent WHO briefing note on data exclusivity for your reference. All the information and evidence points out that data exclusivity can have an immense impact on people's access to medicines and health care. So, please stop any attempts at bringing 'data exclusivity' into our legislation.

In case you need more information, please contact us.
Thank you.

Sincerely,

Naveen I. Thomas
Health Policy Fellow

Encl:

1) The Report of CIPRIPH
2) MSF)'s briefing note on data exclusivity
3) WHO briefing note on data exclusivity

Main Identity

From: "Mira Shiva" <mirashiva@yahoo.com>
To: "Dr.B.Ekbal" <ekbalb@gmail.com>
Cc: "Naveen" <navthom@gmail.com>; "Abhay Shukla" <abhayseema@vsnl.com>
Sent: Tuesday, July 04, 2006 12:02 AM
Subject: Re: [pha-ncc] Re: DATA EXCLUSIVITY DRUG POLICY

Dear NAVEEN ,
I HAD NOT RECEIVED THE ORIGINAL DRAFT . ARE YOU SURE THIS IS THE FINAL ONE FROM YOUR SIDE BECAUSE THE FEEDBACK RELATED TO GENERICS , DR MASHELKAR , DRUGS & COSMETICS ACT HAS NOT BEEN INCORPORATED
CHANGE THE HEADING IT SHOULD BE " REJECTION OF DATA EXCLUSIVITY A TRIPS PLUS MEASURE HAVING NEGATIVE PUBLIC HEALTH IMPLICATIONS>"

I made the changes on the draft but I am not able to send it .
I am therefor retyping it .
No 4 should be no 1clearly stating that 39.3 of TRIPS deals with DATA PROTECTION &DATA EXCLUSIVITY is TRIPS PLUS.
Pg 2 last para Pg 3TRIPS PLUS PARA PLEASE DELETE MENTION OF VICE CHAIRPERSON DR MASHELKAR Reasons already given.
Pg 3 UNethical Practice line 2 instead of generic change it to GENERIC EQUIVALENT DENIAL OF REASONABLE PRICED GENERIC EQUALENT(THESE COULD BE NON ORIGINAL BRAND DRUGS), TO NUMEROUS OTHER PEOPLE who cannot afford costly drugs. ORIGINAL for which MARKETING LICENSE is given .MANY OF THESE DRUGS BEING THOSE WHOSE PATENT PROTECTION PERIOD HAS EXPIRED.
US ING DRUG CONTROL INFRASTUCTURE TO DO POLICING FOR PHARMACEUTICAL COMPANIES FOR DATA EXCLUSIVITYTHROUGH AMENDMENT OF THE DRUGS & COSMETICS ACT IS UNETHICAL WHEN THE DRUG REGULATION NEEDS STENGTHENING , AS THE ISSUE OF QUALITY , ENSURING GMP , GLP,ADVERSE DRUG REACTION MONITORING need to be addressed moreeffectively.
pg 3HEALTH CARE COSTS
1st line In a country where ADD THE STATE HAS FAILED TO PROVIDE HEALTH CARE SERVICES TO ITS MILLIONS,& WHERE MEDICAL INDEBTEDNESS IS EMERGING AS A MAJOR CONCERN .
Pg 4OPPOSITION FROM WITHIN
1st LINE CHANGE IT TO
CONCERN BY IPR & PUBLIC HEALTH EXPERTS INCLUDING MINISTERY OF HEALTH

NAVEEN ARE YOU SURE THIS WAS THE FINAL VERSION .
It is too long . It COULD BE MORE PUNCHY . WE MAY NEED TO LOOK AT IT ONCE MORE BEFORE SENDING IT
REGARDS
MIRA SHIVA

NT - for action

RN
5/7/06

7/4/2006