DATA EXCLUSIVITY

- A CASE STUDY TO SHOW HOW TRIPS-PLUS INTELLECTUAL PROPERTY RULES AFFECT ACCESS TO MEDICINES

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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.

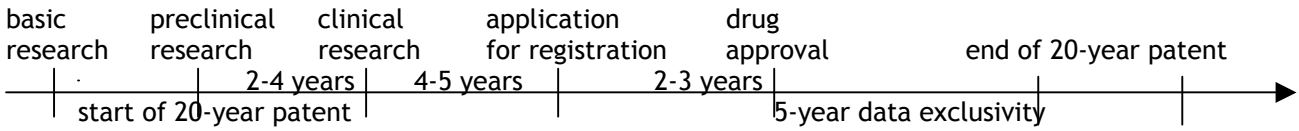
Data exclusivity is a means of impeding generic competition, and maintaining artificially high prices, thereby restricting access to medicines. Moreover, it could be considered unethical to require generic manufacturers to conduct their own safety and efficacy trials with proven effective compounds. 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?

[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.

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.

World Health Organization
Regional Office for South-East Asia

Briefing Note
Access to Medicines

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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.

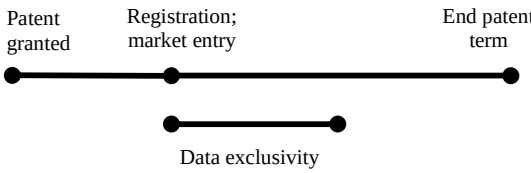
Alternatively –and in practice much more likely– generic producers would have to delay the launch of their product until the end of the exclusivity period[1]. Thus, data exclusivity diminishes the likelihood of speedy marketing of generics, and delays competition and price reductions.

[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

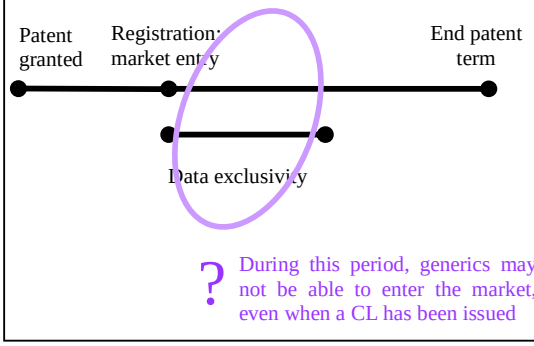
Proponents of data exclusivity at times point out that data exclusivity does not have major implications, since the period of data exclusivity would normally be shorter than the patent duration (see Figure 1a).

Figure 1.a.: "standard" situation



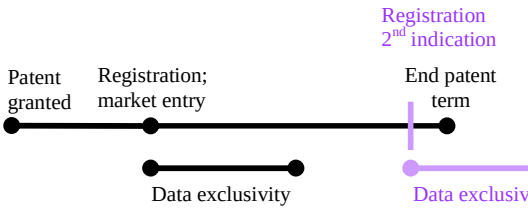
Yet, there are some questions as to whether data exclusivity could prevent the registration of medicines produced under a compulsory license (see Figure 1b). If so, data exclusivity would effectively render the compulsory license useless.

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.

REFERENCES AND FURTHER READING

1. Carlos M. Correa. Protection of Data Submitted for the Registration of Pharmaceuticals: Implementing the Standards of the TRIPS Agreement. Geneva: South Centre/WHO, 2002. Available at http://www.southcentre.org/

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3. MSF. Access to medicines at risk across the globe: what to watch out for in free trade agreements. Medecins Sans Frontieres, May 2004. Available at http://www.accessmed-msf.org/

4. Robert Weissman. Public health-friendly options for protecting pharmaceutical registration data. International Journal of Intellectual Property Management (forthcoming).

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.

****

[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.