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Data Exclusivity: An Absolute Monopoly

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ABSTRACT

The paper describes data exclusivity, its implication on generic drug manufacturers, and on cost of life-saving drugs in developing countries like India.

Keywords: Data exclusivity, patent act, DRA, DCI, ARV

1. INTRODUCTION

Data exclusivity (DE) refers to test and other data that a pharmaceutical company must provide to the concerned national Drug Regulator Authority (DRA), in order to get first time registration for any new drug it wants to introduce in the market of that particular country. These tests are necessary to demonstrate the safety and efficacy of the drug. After registration by DRA the drug gets into the market for use by the public. When generic manufacturers later apply to register another version of an already-registered drug, they only have to demonstrate that their product is equivalent to the original. For this the generic drug companies use the tests that have already been conducted by multinational drug companies.

To limit generic competition, multinational drug companies are demanding that they should have exclusive right over their test data and are pushing for DE measures that will even prevent the DRA from relying on test data already in their possession for subsequent approval of generic versions of the drug. Therefore, DE measures imply much more than non-disclosure of test data by the DRA to rival pharmaceutical companies. The US Government under pressure from the Pharmaceutical Research and Manufacturer of America (PhRMA), the organisation representing the interest of the United States of America's multinational drug companies, is seeking data exclusivity legislation from countries including India to provide 'exclusive rights' over pharmaceutical test data for a period of five years or more. This will only further strengthen the hold of multinational drug companies over drug pricing, and will have grave ramification in developing countries like India where the live-saving drugs will become beyond the reach of the poor people.

2. IMPLICATIONS OF DATA EXCLUSIVITY

Data Exclusivity measures extend the period of patent protection for drugs beyond the stipulated 20 years, adversely affecting

access to affordable generic drugs. Once the legally stipulated 20 years of patent protection is over, the pharmaceutical companies will not be able to undertake clinical trials to obtain marketing approval to manufacture and sell these generic drugs. Therefore if clinical trials are mandated in India for generic manufacturers, it will ensure that the process of marketing approval takes a few more years that are required to undertake and complete clinical trials. This will automatically ensure an extension of the patent monopoly on the drug for the patent holder.

Public interest groups, like Doctors Without Borders are concerned that DE measures will impact access to generic drugs as they are designed to limit generic competition and the ability of the government to make use of safeguards in their patent laws to protect public health. DE measures in other countries are already preventing drug regulatory authorities from granting approval to generic medicines for up to 5-10 years seriously delaying access to affordable generic versions of drugs.

In Guatemala in February 2004, *Atazanavir,* an anti-retroviral (ARV) drug (priced at US$ 10, 000 per person per year) received data exclusivity protection for five years under the law passed by the Government. With generic competition the price can be expected to fall by approximately 95 per cent. However, even if a more affordable generic version of *Atazanavir* is developed, it cannot enter the Guatemalan market until 2009 as drug regulatory authorities have to provide DE protection to test data related to *Atazanavir*. As a consequence, DRA in Guatemala is barred from relying on it to approve subsequent generic versions.

3. IMPACT OF DATA EXCLUSION ACCESS TO INFORMATION

The DE protection is being advocated by multinational pharmaceutical companies on the basis of commercial reasons. This is being done without considering the importance of public access to pharmaceutical test data. Data exclusion protection in law implies that patients will have no access to the results of safety and efficacy tests of the medicine that they are taking. However, till date, for any new drug, which is released into the market, data and research related to efficacy and toxicity is considered public property.

4. INDIA AND DATA EXCLUSIVITY

As of now, there are no DE provisions in Indian law. As per current practice in India, generic manufacturers have to apply for marketing approval of the generic version of a medicine to the DRA of India. They are only required to provide simple and straight forward studies to prove that their generic version of the medicine is the therapeutic equivalent to the original and thus they do not need to re-submit test data regarding safety and efficacy, which is already with the DRA. For this, the DRA is entitled to rely on test data submitted by the pharmaceutical company who first sought marketing approval for the medicine.

The government of India is considering amendments to the Drugs and Cosmetics Act, under pressure from the US, European countries and multinational pharmaceutical companies to amend the act to include DE protection provisions. If such DE provisions are introduced in the Drugs and Cosmetics Act, the Drug Controller will be barred from relying on test data, which is already in its possession in granting marketing approval to generic medicines. Instead, it will be forced to ask the generic manufacturer to carry out its own clinical trials showing efficacy and safety of the medicine thus seriously affecting the production of affordable generic medicines in the country.

5. CONCLUSION

The right to information bill has been passed in the parliament with much fanfare and media coverage. But simultaneously the Prime Minister Office is contemplating to amend the Drugs and Cosmetic Act, as it is buckling under pressure from the US, and granting of DE, which in a larger sense

means that generic drug manufacturers will not be allowed to get the drug data testing information for a definite period of time. Thus, there will be no competition, as no generic manufacturer will be able to make it. This will give absolute monopoly to the multinational drug companies.

If the Right to Information is a step forward then granting of DE is taking us several steps behind (with regard to access to life and essential saving medicines).

One wonders if the laws of this country are being remade to help the US-based drug industry. It is for the people and our political leaders to take up this issue. Because right to life saving and essential medicines is a part of Right to Health, which is enshrined in our constitution.

Contributor

Dr Gopal Dabade has obtained MBBS, Diploma in Laryngo-Otology, and Postgraduation in ENT. He has worked with various rural non-government development agencies as In-charge of Community Health Projects like India Development Service, India's New Group for Raichur's Integrated Development, Hubli Hospital for Handicapped in Karnataka,as a Lecturer for basic science at Human Anatomy Department at the SDMCDS, Dharwad, Karnataka, and as a health activist in BUKO Pharma-Kampagne, Bielefeld, Germany. Presently, Dr Dabade is working at SDM Medical College, Dharwad, and is also President, Drug Action Forum, Karnataka—a State level campaign group committed to rational drug therapy and drug policy.