



## Back to the Future: Talking to Your Medicine

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### ABSTRACT

Drug Business is perceived as a risky business, even though in the last few decades medicines have become increasingly safe and efficacious. Though uncommon, there is always a chance that any given medicine can fail to meet its standards or induce undesirable side effects. The regulatory controls over medicines are generally influenced by many factors such as consumer pressure, politically interests, false and misleading advertising and results of many tragedies caused by many medicines. Drug safety has been and will continue to be an important issue. All medicines used by consumers have risks and it is important to balance this risk against the expected benefit. The safe production of medicines and control is the primary responsibility of manufacturers. However, this responsibility should not be left to the manufacturer alone but also shared by the government in order to protect the consumer against health hazard and various forms of exploitation. Of fundamental importance are the regulatory framework and its requirements being practical, realistic and directed towards the protection of the consumer from ineffective and poor quality medicines. The point is that health and safety are of paramount importance and should not be compromised. Proactive risk management strategies are important both before and after the approval and marketing of medicines.

**Keywords:** Generic drugs, medicines, regulatory.

### INTRODUCTION

In the interest of consumer protection, government policies towards medicines have progressively removed control of medicine choices from the consumer. However, on the other hand tremendous progress has been made by the pharmaceutical industry in the development of highly effective medicines to treat many fatal diseases.

There is no doubt that innovation has played an important role in pharma companies developing efficacious medicines but at the same time they have reaped the intellectual property protection. The generic manufacturers producing branded generics have contributed equally to realize public health programs' goals of accessibility and affordability.

The regulatory controls over medicines are influenced by many factors such as consumer pressure, politically interests, false and misleading advertising and results of many tragedies caused by many medicines.

Consumers are concerned about the safety of medicines, as too many suffer from unexpected and unpreventable adverse events from these medicines. However, drug safety has been and will continue to be an important issue. All medicines used by consumers have risks and it is important to balance this risk against the expected benefit.

#### Fortune Magazine's unfortunate take on generics

An article, "Are generics really the same as branded drugs?" appeared in January 2013 in Fortune magazine. The article was written by Katherin Eban<sup>1</sup>. It is started

with the recent action of US FDA on the Teva Pharmaceuticals popular anti-depressant, Wellbutrin, which is found to be non-bioequivalent to the brand version. This article has brought a momentum where doctors and medical services are questioning the quality and the trust placed on generic products.

In essence, the whole article is more or less anti-generic in nature, thus taking us back to the future when a major controversy against generics was started during late 60's and early 70's. Such articles giving examples of certain quality and/or efficacy failures of generic drug is inappropriate because there are 100s and 1000s of failures of batches of pharmaceutical products including a number of innovator products, which fail to meet quality, efficacy and safety standards.

In the case of Levothyroxine, there is a high probability that potency variations within product batches may occur. It is very difficult to establish the therapeutic equivalence of this drug; physicians should exercise caution when switching brands in this therapeutic class. The example of Ranbaxy is not specific to a generic drug company, similar quality issues have happened with many Innovator manufacturers as well. It is not ethical to use examples targeting credibility of generic companies.

#### What is a Generic Medicine, really?

A generic medicine is a chemical copy of brand named medicines. There are generic versions of both prescription and over the counter medicines and these generic medicines are approved by regulatory authorities after proper assessments of quality, safety and efficacy. It is expected that these generic medicines have the same



therapeutic effect as their brand named counter parts. Furthermore, these generic medicines have exactly the same dosage forms, intended use, side effects, route of administration and safety profile. They also contain identical medicinal ingredients and have the same strength as the original or innovator medicine. However, these generic medicines are much cheaper than the innovator and play an important role in the healthcare sector of any country.

Regulatory authorities make assessment of the quality attributes<sup>2</sup> identical to that of innovator medicines. In lieu of their clinical trial, the efficacy of generic medicines is established by comparative bioavailability and bioequivalence studies. Thus if we compare innovative and generic medicines with respect to quality, safety and efficacy, we will not find significant difference.

### The role played by the History of Drug and Devices

If we compare innovative and generic medicines with respect to their quality and safety or health hazard caused by these products, we will note that many major tragedies are caused by the innovators products and not by generics. Let us review some of these tragedies to understand how these incidents are associated with the regulatory changes, bringing a new dimension of the safety and efficacy of medicinal products.

The two products, one drug and other medical device in the early of the 20<sup>th</sup> century are synonymous with injury and sorrows, the children of Thalidomide, who suffered and are still suffering. In 1990 after 28 years, Canadian sufferers received 7.5 million dollars in federal compensation.

In the area of medical devices, Dalkon Shield is the ranking tragedy in which about 4 million women used this simple plastic contraceptive device that fit into the uterus. The device was developed by Dalkon Corporation and marketed with no safety tests conducted. Within a year the product caused serious pelvic infection sterility and miscarriages. Thousands of women suffered and many died.

Both Thalidomide and Dalkon Shield prompted changes in regulatory requirements. Thirty years after the two tragedies, came another serious tragedy with C-C valves which caused many deaths.

The meme breast implant has a long controversial and fascinating story of its safety. Beside medical devices, there are large number of medicinal products that have many safety issues. These include Depo Provera, a contraceptive injection of the Upjon Company; Torado characterized as pain killer and downplayed as NSAID by Syntex in Canada<sup>3</sup>; a major side effect of Halcion—intended for short term treatment of insomnia ended in big controversy due to its side effects of depression, anxiety, hallucination and paranoia.

The marketing of this medicinal product, was suspended by the regulatory authority of Britain for not reporting the

side effects which were known to the company. And then the recent Viox case. Almost all of these products represent inadequate safety testing and are associated with the innovators.

### If Truth Be Told

An article from William Haddad<sup>4</sup>, is an important piece of work on some incredible issues related to the generic version of HIV drugs.

In his 2003 State of the Union address, President Bush told to congress: “Because the AIDS diagnosis is considered a death sentence, many do not seek treatment. Almost all are turned away....A doctor in rural South Africa describes his frustration...many hospital tell people, You have got AIDS. We can't not help you. Go home and die “ He further said, “No person should have to hear those words—the cost of these drugs have dropped from \$12000 to under \$ 300 a year which places a tremendous possibility within our grasp-seldom has history offered a greater opportunity to so much for so many”.

A generic company in India created a fixed dose combination of three most important AIDS medicines, Triomune, reducing daily regime of dozen doses a day from multinational companies to single tablet taken in the morning and another at night cutting the cost from \$15,000 a year to a dollar a day<sup>5</sup>.

A similar controversy has started with Biosimilars, particularly Intraferon, The cases of Hepatitis are increasing very rapidly in the developing countries. If the generic versions are not available at a reasonable cost, thousands of people suffering will die as they cannot afford these medicines. The question is what is the value of developing life saving drugs if they cannot be made accessible to the consumers who are suffering?

### CONCLUSION

There is no doubt that the pharmaceutical industry have moved from the point of treating infectious diseases in an indiscriminate manner to an area where future products will not only prevent but modify and cure diseases.

Both innovator and generic manufacturers have been delivering and contributing in past but will also do-so in the future and will be committed to innovation and benefit to health systems.

Like innovators have contributed towards innovation, generic industry has contributed towards affordability and availability of medicines to millions who otherwise would die.

So let's not re-start this controversy, as we are already going through a similar situation with Bio-similars.



**REFERENCES**

1. Eban, K. Are generics really the same as branded drugs. Fortune magazine January 2013. <http://management.fortune.cnn.com/2013/01/10/generic-drugs-quality/> (Accessed on February 24, 2014)
2. WHO, Quality Assurance of Pharmaceutical. A compendium of guideline and related materials, Volume 2, 1999. [http://www.who.int/medicines/areas/quality\\_safety/quality\\_assurance/QualityAssurancePharmVol2.pdf](http://www.who.int/medicines/areas/quality_safety/quality_assurance/QualityAssurancePharmVol2.pdf) (Accessed on February 24, 2014)
3. Regush, N. Safety Last. The failure of the consumer health protection system in Canada, Toronto: Key Porter Books 1993. P12.
4. William F. Haddad. The AIDS story you may not have heard. <http://www.equilibri.net/nuovo/es/node/2292> (Accessed on February 24, 2014)
5. Hamid, Y. generic drug Boss - The Guardian 18 Feb, 2003 <http://www.theguardian.com/world/2003/feb/18/aids.sarahboseley13> (Accessed on February 24, 2014)

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