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GMOS: Efficacy, safety and profit

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INTRODUCTION

A genetically modified organism (GMO) is a living thing with a novel combination of genetic material obtained through the use of modern biotechnological techniques and different from what is found in nature. These organisms are products of research manufactured for profit for the benefit of mankind. In this regard, there are three players: researchers, manufacturing companies and consumers. It is the role of regulators to ensure that the interests of these three are kept separate and distinct so that the rights of consumer are not violated.

RESEARCH

Researchers have an academic obligation of contributing to the knowledge pool as well as inventions or innovations that result in an efficacious and safe GMOs. In this regard, the research process is guided by good research practices (GRP) which ensure that efficacious products are first tested for safety *in vitro* after which their safety is established in small animals and then primates before final clinical trials in humans. Post market surveillance monitors the product for several generations to ensure its long term safety. These GRP establish GMO safety in respect to vital organs such as the heart, lungs, kidney and liver; allergenicity, mutagenicity, carcinogenicity and teratogenicity in not only humans but also non target organisms.

MANUFACTURING

It is only after these stringent processes that manufacturers develop the GMO as an innovation or invention that is commercialized for use at a profit. As they manufacture the products however, they are subject to good manufacturing practices (GMPs) that protect the consumer. Furthermore, they are required to adhere to the laws of the countries where they market their products. In respect to Kenya, the marketing of GMOs is subject to The Biosafety Act (2009) and the Biosafety (Labelling) Regulations (2012). One of the objectives of the latter is “to ensure that consumers are made aware that food feed or product is genetically modified so that they can make informed choices”. In this respect, all products containing GMOs should be so labeled.

FUNDING AND CONFLICT OF INTEREST

Researchers driven by desire for efficacious and safe inventions and innovations must thus be independent from manufacturers driven by profit for an absence of this independence may present a conflict of interest which may compromise safety. This is however theoretical for most multinational manufacturers have research and development programs that blur the separation of these two concerns. Furthermore, research funding in institutions is always inadequate to meet the expensive requirements of for example the development of a product and thus researchers often turn to manufacturers for funding with an agreement of exclu-

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sive rights over emanating inventions or innovations. It is thus possible to have a GMO researched, (or research funded by) developed and marketed by the company. Lack of separation of efficacy, safety and profit driven concerns provides an ethical dilemma due to obvious potential for conflict of interest from the various players.

REGULATORS AND CONSUMER RIGHTS

Such a conflict of interest may be to the detriment of consumers violating their rights as stated in article 46 of the Kenyan Constitution that “Consumers have the right to goods and services of reasonable quality; to the information necessary for them to gain full benefit from such goods and services; to the protection of their health, safety, and economic interests; and to compensation for loss or injury arising from defects in goods or services”. The National Biosafety Agency (NBA) is thus a regulator funded by the exchequer to ensure that these interests are taken care of and rights protected. The NBA mandate states it has a role to “co-ordinate, monitor and assess activities relating to the safe transfer, handling and use of genetically modified organisms in order to ensure that such activities do not have adverse effect on human health and the environment”. Thus, NBA should ensure the safety of consumers from invention/innovation-driven researchers and profit-driven manufacturers. To play this role successfully, the NBA must be separate and distinct from the two for a lack of independence would result in a conflict of interest that compromises the safety of humankind.

CONCLUSION

The GMO debate is about these three players: researchers, manufacturers and regulators in respect to efficacy, safety and profit. In this regard, it is important to get answers to certain crucial questions. Have researchers adhered to GRPs that ensure that GMOs are both efficacious and safe? Have multinationals followed GMP and the laws of the country to ensure informed decisions by consumers? Is production of GMOs efficacious for benefit of mankind or just for the profit of the manufacturer? Are products containing GMOs in the market labeled appropriately? But even more important are questions of independence. Are researchers, manufacturers and the NBA separate and distinct? For instance, who paid for the clinical trials for the Bt cotton, Bt maize and the Roundup ready maize? Can we be assured that there was no ethical dilemma and the researcher was totally independent of the manufacturer? Is the NBA independent and diligent to ensure that the rights of consumers are not violated? As Kenyans, the bottom line is an assurance that efficacy of GMOs and their safety has not been compromised by profit.