Regulatory Theory

Briefing Note: Outcomes in A Free Market in

The Absence of Government Regulations of the Pharmaceutical Industry

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BRIEFING NOTE:
OUTCOMES IN A FREE MARKET IN THE ABSENCE OF GOVERNMENT REGULATION OF THE PHARMACEUTICAL INDUSTRY

PURPOSE

To assess the outcomes in a free market for the public and the pharmaceutical industry in the absence of government regulations through Health Canada's Food and Drugs Act (FDA) that guides the production, import, export, transport, and sale of drug products in Canada.[2]

BACKGROUND

A true free market is one that ideologically is based on the mutual understanding and agreement of the terms involved in the transaction between the buyer and the seller, or supplier. In this system, the state does not exercise any intervention based on market regulations.[4] Unfortunately, this utopian ideal is not feasible. Both the free market and the state are interdependent components of the marketplace, with the existence of the free market being dependant on regulation by the state.[4] This ensures that the market functions with controls in place, and that there is confluence of transactions between buyers and sellers. This in turn allows the system to remain as a free market by preventing exploitation of the economic system by participants that do not act in accordance with the requirements of the free market.

CURRENT STATUS

Health Canada is the branch of the Government of Canada that is responsible for ensuring the availability of high-quality health services to Canadians, while reducing exposure to health risks.[3] The FDA provides the regulatory framework through the Food and Drugs Regulations (FDR), which establishes the requirements for the manufacture, packaging, labelling, storage, sale, and importation of prescription and non-prescription pharmaceutical products in Canada.[1] The FDR also establishes the regulatory requirements for conducting clinical trials and assigns a Drug Identification Number (DIN) to pharmaceutical products that receive market approval through Health Canada.[1]

KEY CONSIDERATIONS

In the absence of the regulatory authority of Health Canada:

- There would be no establishment and maintenance of a drug product database (DPD) containing product monographs with current information to guide consumers and health care professionals on the availability of medicines. [1]
- Therapeutic classification of drug products and identification of therapeutically equivalent agents would not be available to guide usage.
- The assignment of drug schedules through the FDR, which differentiates controlled drugs and substances, radiopharmaceuticals, and other drug types would not be established, and there would be no specific guidelines concerning their handling and sale.[2] As a result, these drugs would be freely available on the market and the sale and usage would not be monitored or controlled leading to negative outcomes.
- Advertising of drug products would be allowed, and there would be no certainty that a drug product with an advertised claim of efficacy would achieve any clinical effectiveness, leading to confusion among consumers.
- Monitoring of serious adverse events would not be available to guide warnings, precautions, contraindications, and drug withdrawals. Therefore, market withdrawals of the drug product due to serious adverse effects will not occur, resulting in unsafe drug products being on the market.
- There would be no regulations governing the use of drug products for human verses veterinary use.
- Good Manufacturing Practices (GMPs) in drug production would not be monitored to ensure the safety of drug products on the market.
- Clinical trial data that guides whether a drug is approved would not be assessed in the process of drug development. This would result in unsafe drugs or drugs that are not therapeutically efficacious being on the market. With the absence of any regulation such trials may not even be conducted, which would compromise the quality of medical care.
- Post marketing surveillance of drugs would not be required, therefore, monitoring data for the adverse effect profiles and therapeutic efficacy over time would not be available to guide drug use.
- Generic drugs that are therapeutically equivalent to trade name drugs may not be given the opportunity to enter the marketplace if conditions for a monopoly exists. The entry of generic drugs into the market helps to control the price ceiling for drugs, which effects affordability of pharmaceuticals. Regulation allows the public to have confidence that the efficacy of generic drug products is similar to trade name drugs.
- There would be lack of public trust in the pharmaceutical industry due to negative patient outcomes, and this would compromise the integrity of the pharmaceutical industry, and the field of medicine.

- There would be no monitoring or control of the importation of pharmaceutical products, resulting in unsafe pharmaceutical products and products lacking therapeutic efficacy to enter the market.

CONCLUSIONS

The pharmaceutical industry cannot function in the absence of state regulation and must be a highly regulated area to protect the health and safety of the public. This regulation is also necessary to provide private stakeholders with the regulatory infrastructure to ensure safe and therapeutically efficacious pharmaceutical products are developed through clinical trials, and GMPs are followed during drug production. Therefore, the pharmaceutical industry must be regulated by Health Canada, a necessary regulatory authority to ensure that safe and effective drug products are available in the marketplace.

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