



Faculty of Commerce and Management Studies

Bachelor of Business Management (General) Degree

Year II Examination (External) - 2008

BMGT E 2065 / BMGT 23065 - Organization Theory and Design

No. of Questions: 07

Time: 03 hours

Answer any five (05) questions only.

(01) Restructuring of Drug Administration Institute.

Through vitamin pills that are used to enhance beauty of woman are much popular among, women, Food and Drug Administration (FDA) has not given the approval for those vitamin pills. While drugs manufacturers have been assured that FDA approval would be granted, they are reluctant to spend the requisite time and money on the FDA's notoriously lengthy application process. Unfortunately, this is not an isolated situation. FDA'S red tape has prevented many potentially beneficial products from entering Sri Lankan market. This is a serious problem, considering the wide scope of the FDA's jurisdiction, over food, food additives, drugs and medical devices, TVs, microwave ovens, and pet products, accounting for \$ 960 million worth of goods.

Dr. Lalith Gunawardhane who took over as commissioner in 2000 made it his turn to change the things around at the FDA. In addition to bringing FDA practices up to speed, Dr. Gunawardana confronted the difficult task of restoring the agency's credibility and morale after 1999 generic drug scandal, which ended in the conviction of four FDA employees for taking " illegal gratuities." In order to restore faith in the agency, his first steps included cracking down on everything from falsely labeled "fresh" orange juice to allegedly dangerous diseases.

Then came the formidable challenge of streamlining the cumbersome bureaucracy that had traditionally plagued the FDA. Dr. Gunawardhana began by delegating authority to the 21 field offices, empowering the lower level FDA managers, and reducing the frequency of review by headquarters. This enabled the FDA to expedite enforcement actions and drug reviews. Moreover, the time necessary to process injunction requests was reduced by 60 percent. Dr. Gunawardana also acquired cabinet approval to bill companies for drug evaluations, and thereby increased the FDA's 2003 budget to \$826 million, up 8.7 percent from the previous year. Extra reviewers were then hired in an effort to cut the average drug approval time from 22 months to 12 months by 2008.

In order to transform the FDA into a more efficient regulator, Dr. Gunawardhana borrowed what he called “ the best practices of the private sector.” This has involved rehiring, reorganizing, and restructuring. From 2000 to 2003, total staff grew from 7800 to 9000. “The first day I got here, I was called to the Health & Human Services Ministry” recalled Dr. Gunawardhana. “For a whole day, nothing else got done.” He immediately put five deputies in place to oversee policies, manage crises, deal with Health Ministry and the outside world, handle daily operations and, overhaul the agency’s ancient communications systems. “In the past, management (at the FDA) meant doing the budget, allocating office space, and doling out parking spots,” remarked Dr. Gunawardhana.” The agency never asked how work should get done.” Under Dr. Gunawardhana this has changed.

In addition, Dr. Gunawardhana has focused the FDA’s centers for biologics and foods on products approval by reorganizing them around products instead of scientific disciplines. This resulted in the on-time implementation of the 2000 Nutritional Labeling & Education Act. Instead of having food-labeling expertise scattered throughout the FDA, Dr. Gunawardhana restructuring placed it all in a single division. “ We would never have gotten food labeling done had it not been for the reorganization,” said Food Safety Center Director Ranjith Perera.

Dr. Gunawardhana has also made the FDA more user-friendly. Each agency center previously had its own forms and requirements for companies wishing to report adverse reactions to products. Now, all of the centers share the same forms and requirements and interaction is encouraged between similar divisions who formerly worked autonomously. though previously these centers worked independently, after reorganization dr. Gunawardhana was able to make good coordination between centers.

But there could be a downside to a more efficient FDA. Many people have expressed concern that expediting the FDA’s approval process will result in an increase in potentially harmful drugs being made available. “The public has traditionally expected FDA to keep unsafe and ineffective drugs from being approved and marketed,” Meril De Silva vice-president for medical and regulatory affairs for the Human health Services Association, pointed out. “ There has been a growing recognition of the other side of consumer protection, and that is to approve safe and effective drugs in a timely manner. As the Agency beings to move towards more rapid approval, there will also be highlighted expectations of the FDA to monitor the safety and efficacy of drugs after approval.

Recognizing this, Dr. Gunawardhane has responded with the implementation of MEDWatch, a program designed to encourage voluntary reporting of adverse reactions by health professionals. “(This) is not just a new FDA System,” Dr. Gunawardhane noted, “It is a way of making reporting of adverse events and product problem a part of the culture of healthcare providers. Physicians, nurse and others who care patients are the first to know when a drug medical device does not perform as it should. The sooner they report it to FDA, the faster the agency can analyze the problem and take corrective action.” MEDWatch is designed to correct for the fact that health professionals are not legally required to report and that as many as are not even aware that they can report. MEDWatch is symbolic of the great strides taken by the FDA under Dr. Gunawardhane’s influence.

I What were the external and internal factors that influenced Dr. Gunawardhane’s management decision? Explain

(08 Marks)

II Which organization design does Dr. Gunawardhane appear to be following? Discuss.

(10 Marks)

III Analyze the FDA from a systems perspective. How does Dr. Gunawardhane’s management indicate that he is aware of the FDA as of a system?

(10 Marks)

(02) a) Contrast Taylor’s and Fayol’s organizational analysis.

(09 Marks)

b) Is Open- Systems Perspectives superior to the Closed System Perspective? Describe.

(09 Marks)

(Total 18 Marks)

(03) a) “Goals are a viable standard against which organization effectiveness can be measured.” Build an argument to support this statement.

(12 Marks)

b) Are organizational efficiency and flexibility conflicting goals? Explain.

(06 Marks)

(Total 18 Marks)

(04) a) Describe the organizational decision making process. Is it different from the individual decision making process? Discuss.

(12 Marks)

b) Discuss the advantages and disadvantages of centralization.

(06 Marks)

(Total 18 Marks)

(05) a) Compare Machine Bureaucracy and Professional Bureaucracy.

(09 Marks)

b) By showing the characteristics of Divisional Structure, explain the instances where it can be applicable.

(09 Marks)

(Total 18 Marks)

(06) a) What is the relationship between Technology, Size, Industry and Structure?

(09 Marks)

b) Why do managers dislike environmental uncertainty? What can they do to minimize it?

(09 Marks)

(Total 18 Marks)

(07) Write short notes on any three of the following topics.

Bureaucracy

Flexibility

Hawthorne Studies

Diversification

Power Sources

(06x 3 Marks)

(Total 18 Marks)