Public Sector

Drug Regulatory Authority

Introduction

Most countries have a Drug Regulatory Authority or similar entity tasked with regulation of medicines, especially regarding importation of drugs, compliance of retail pharmacies, and control of black market or counterfeit medicines. It is often helpful to interview a representative from this agency to gain an understanding of the pharmaceutical landscape and procurement issues.

Questions

- What is the registration process for new health products? How long does it take? Does it differ by class of health product?
- Are there government controls on pricing to ensure access for the poor?
- Are these controls in place in both the public and private sector?
- What is the process to obtain a license to manufacture products in the country?
- How are products certified?
- Are there restrictions on importing products?
- What is the process to obtain a license to distribute products?
- What are the tariffs for sales in the private sector?
- Are there any classes of products that are exempt?
- What have been the greatest challenges related to standards for health products in the country?
- How do you ensure the quality of distributed products?