

## **Case Study:**

### **Challenges in The Pharmaceutical Value Chain in Bastania**

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*This case represents a fictionalized and composite version of possible events and circumstances that might exist in pharmaceutical markets around the world. This case is intended for teaching purposes only. All names and places in this case are fictional.*

#### **Introduction**

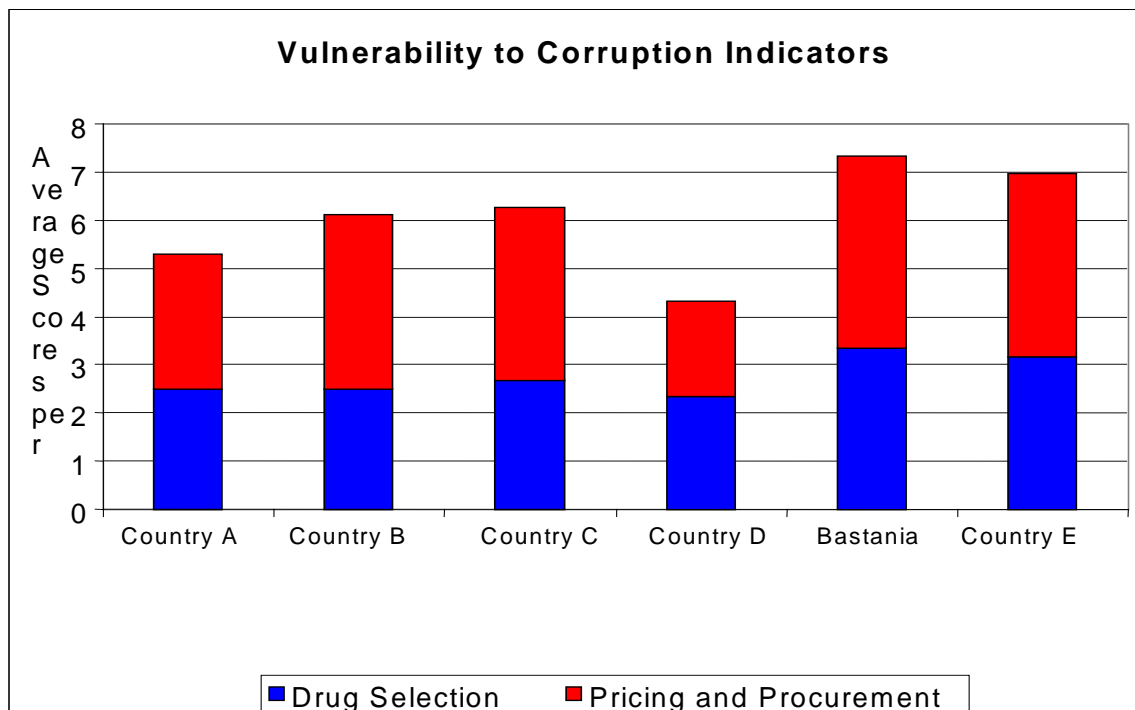
1. It was April 1, 1998. John Pilson, a World Bank task manager, stared at the report of drug manufacturer complaints lying on his desk. All of the complaints related to the pharmaceutical supply chain in Bastania, and, although individual manufacturer experiences differed, they all revealed inefficiency and a lack of transparency across the system.
2. Now these problems had become Pilson's main concern. In late 1997, the World Bank had extended a development policy loan (DPL) to Bastania to, inter alia, strengthen the pharmaceutical system such that financial sustainability, efficiency, and access to affordable medications were all enhanced. Analytical work associated with the DPL had revealed that Bastania was paying much more for pharmaceuticals as compared to neighboring countries, and out-of-pocket payments were high. Although Bastania's market was small, Pilson was concerned that the high prices might be linked to inefficient procurement and pharmaceutical pricing policies, unethical behaviors, or outright corruption. Pilson's concern was heightened after he read the report of drug manufacturer complaints.
3. Pilson was glad to be working closely with Mikhail Kachanik, Bastania's reform-minded Deputy Minister of Finance. Kachanik had been appointed by the President of Bastania, Dimitry Azak, who was elected in 1990 on a platform of reform. Along with the President, Kachanik's goal was to bring Bastania's public policies in line with those of the European Union. Kachanik was intensely interested in the issue of impediments in the pharmaceutical supply chain, especially after receiving a complaint from a drug manufacturer who complained that procurement in Bastania was rigged in favor of local competitors.
4. Kachanik had tasked his staff with investigating this complaint; the investigation confirmed that this complaint was not an isolated incident. The findings of the investigation were described in the complaint report that Pilson had just reviewed. The report now crystallized a question that had been growing in the minds of both men: were these inefficiencies due to a lack of institutional capacity, ineffective laws and regulations, unethical behaviors, or outright corruption?

5. Kachanik was suspicious, and promised Pilson he would ask his staff to investigate further. “It is important for us to define the real issues hindering the efficacy of the pharmaceutical supply chain, so that we can address them appropriately,” Kachanik asserted. “Manufacturers prefer a business environment in which processes are clearly outlined and officials perform their jobs honestly. If we are to manage health expenditures and encourage international investment, we must ensure that Bastania’s pharmaceutical supply chain is transparent, efficient, and free of corruption.”

*Corruption: Possibility or Probability?*

6. After reading the report, Pilson had a sinking feeling. He sensed that corruption was occurring in Bastania – and from his work in other countries, Pilson knew that the consequences of pharmaceutical system corruption were significant. Corruption at critical points in the pharmaceutical supply chain significantly limited access to quality medicine, with important implications for health. Corrupt practices meant that public spending on medications was excessive and was not based on rational criteria such as cost-effectiveness, safety, and efficacy; corruption also inflated out-of-pocket drug costs. Finally, corruption increased the market presence of counterfeit drugs, leading to serious health consequences and even death. Typically, the poor were most susceptible to the detrimental effects of corruption.

7. In fact, Pilson suspected that pharmaceutical corruption had flourished in Bastania. His suspicions strengthened when Kachanik sent him data from a regional corruption vulnerability assessment indicating that Bastania had the highest vulnerability to corruption based on indicators of drug selection, pricing and procurement (Figure 1):



Source: Mrazek, Monique and Armin Fidler. "Market Structure, Corruption and the Pricing of Pharmaceuticals in the Balkans: Lessons in Deregulation and Re-regulation." Presentation. The World Bank (undated). ).

8. "Once your team investigates the possibility of corruption at each point in the pharmaceutical supply chain, the World Bank team will work with you to design reform strategies that will achieve pharmaceutical cost control while establishing integrity in the process," Pilson told Kachanik. "If implemented well, our reforms will improve access to drugs, reduce medication expenditures, and improve Bastania's credibility in the eyes of other governments and international organizations."

### **Economic and Political Setting**

9. Pilson considered Bastania's circumstances as he awaited the results of the second round of investigation.

10. Bastania was a parliamentary democracy, with an emphasis on civil freedoms, public elections, and a division of government into executive, judicial, and legislative branches. The country had peaceful relations with surrounding nations, and was generally trying to strengthen its relationship with the European Union.

11. Unfortunately, Bastania's history had been characterized by political instability and lack of stewardship due to the brief tenures of a succession of prime ministers as well as many of the country's top departmental ministers. Prior to President Azak's election, governmental leaders had had neither the desire nor the political power to implement real reform.

12. Another source of instability stemmed from the fact that almost half of Bastania's economy was represented by an informal sector; only about 55% of GDP came from the formal sector. During the 1980s, the country had sustained a budget deficit of about 5%, prompting public service cutbacks and a compression of public sector salaries. To achieve financial stability, upon taking office President Azak had instigated reforms focusing on reducing the deficit, increasing governmental efficiency, and strengthening the formal market economy through such activities as centralization of public services and institutions, deregulation and promotion of international trade and investment.

13. Yet another concern was the country's high rate of unemployment, at about 29%. Although Bastania was considered a middle-income country, growth in unemployment had meant a corresponding growth in the population living in poverty.

### **Health Sector**

14. Prior to President Azak's reforms, the country had had a decentralized health system in which hospitals and pharmacies were operated at the municipal level; health care financing had also been handled at the local level. This system led to significant

duplication of effort, problems with alternating over- and undersupply of resources, corruption, and excessive health care costs.

15. President Azak's government created a centralized health care system that provided universal coverage to all of its four million citizens. As part of this new insurance-based system, citizens were provided with comprehensive coverage for primary care, as well as some coverage for secondary and, to a lesser extent, tertiary care. Because the benefits package was comprehensive, it was quite costly, prompting the need for health expenditure management. The primary goal of the new government was to maintain the comprehensive benefits package while ensuring financial sustainability through improved efficiency and cost effectiveness. Another goal was to transition the health care sector from a paper-based management information system to an electronic system, using funds gained through careful expenditure management. It was also hoped that improved health policy would increase Bastania's average life expectancy at birth (73 years) to a level comparable to that of neighboring countries (78 years).

16. The Ministry of Health served as the main regulatory body of the health system; its responsibilities included setting health policy, overseeing health care providers and systems, and monitoring health system performance. The Minister of Health, Marko Vidosava, had been a practicing physician prior to his appointment. The Ministry of Finance was responsible for approving the Ministry of Health budget each year.

17. Under the Ministry of Health, an extra-budgetary fund called the Health Insurance Fund collected payroll-based health insurance contributions, procured pharmaceuticals and supplies from manufacturers, and disbursed funds to public health care institutions. The Health Insurance Fund was responsible for funds equaling approximately 7% of GDP. The Director of the Health Insurance Fund, Ivan Prilip, was appointed by the Cabinet. Although Health Minister Vidosava's responsibilities included reviewing the operations of the Health Insurance Fund, in practice the Health Insurance Fund was quite autonomous and Prilip had sole authority over its operations.

18. The Health Insurance Fund physically procured pharmaceuticals and supplied them in kind to public pharmacies and hospitals. The Health Insurance Fund also held open contracts with public pharmacies: this meant that pharmacies informed the Fund when a certain amount of a drug was needed, purchased the product directly from a supplier, and then submitted an invoice to the Fund for reimbursement for drugs dispensed. The Health Insurance Fund conducted some broad forecasting of pharmaceutical needs, but did not control volumes; internal controls on what was being supplied and sold were non-existent. Authorities had briefly considered whether the Health Insurance Fund should reimburse patients for purchases from private pharmacies, although this possibility had never been pursued.

19. Doctors, dentists and pharmacists each had their own professional associations, which were responsible for issuing professional licenses and setting codes of conduct. Continuing education was provided to a limited extent by the associations; however, thanks to their deeper pockets, pharmaceutical companies typically provided a vast

majority of the continuing education programs. Officially, the associations were also responsible for monitoring professional conduct, although in practice association representatives retreated when confronted by professional resentment regarding this function.

### **Pharmaceutical Sector**

20. The Bastanian pharmaceutical market was complicated, with numerous steps and many parties involved. Compounding this complexity was the fact that the system was paper-based, making it difficult to track drug products from one point to another.

#### *Pharmaceutical Sector Constituencies*

21. The pharmaceutical sector in Bastania included three local drug manufacturers, 180 drug wholesalers, and approximately 700 pharmacies (Table 1):

Table 1: Pharmaceutical Sector in Bastania and Neighboring Countries, 1997.

<b>Indicators</b>	<b>Bastania</b>	<b>Country A</b>	<b>Country B</b>	<b>Country C</b>	<b>Country D</b>	<b>Country E</b>
<b>Number of significant national manufacturers</b>	4	3	1	0	3	2
<b>Number of wholesalers</b>	180	140	100	75	>1000	60
<b>Number of pharmacies</b>	700	1000	800	16	3000	350

22. There was quite a bit of overlap in professional involvement across the different entities; for example, many Bastanian wholesalers and physicians also owned pharmacies and, interestingly, a local drug manufacturer was a large shareholder in one of the daily newspapers.

23. About 300 public pharmacies were operated via the public health system's network of hospitals and clinics. Public pharmacies sold subsidized supplies of drugs, but were also allocated drugs to sell at market prices.

24. A separate system of about 400 privately-owned pharmacies also existed in parallel. The private pharmacies tended to carry a larger selection of drugs, with more branded drugs and more expensive drugs than were typically available in the public pharmacies.

### *General Process*

25. The Pharmaceutical Regulatory Bureau, a division of the Ministry of Health, was responsible for several functions in the pharmaceutical sector. These included licensing medicines for distribution and marketing; issuing import permits for the importation of medicines; and regulating local pharmaceutical manufacturers. The Pharmaceutical Regulatory Bureau issued licenses to wholesalers, distributors and retail pharmacies, while drug manufacturers were licensed by the Ministry of Industry.

26. Upon obtaining a license for a drug, the manufacturer was allowed to sell that drug in Bastania. However, to be eligible for reimbursement under the health insurance system, the drug had to be listed on the Essential List of Drugs, the national formulary that was overseen by a scientific committee.

27. Drugs were secured via competitive bidding tenders with local and international suppliers. Most tenders were local. Bastania's small size often contributed to a strong nationalistic feeling among its citizens. Not surprisingly, the pharmaceutical procurement process favored domestic over international products, even in cases where international drugs were less expensive and/or higher quality. Very often, the specifications of a tender were finessed to suit local suppliers. In addition, multiple small tenders, rather than few large tenders, meant that the Health Insurance Fund had to assess and administer offers from many pharmaceutical companies.

28. Once drugs were obtained, the Health Insurance Fund distributed them through wholesalers to hospitals and pharmacies via Fund-operated warehouses and transportation systems. Still, much of the procurement by individual pharmacies or hospitals was done on an "emergency" basis (due to poor planning and/or incompetent quantification), usually involving direct purchase from a wholesaler.

29. Although the Bastania Drug Law governed pharmaceutical supply practices, the law had many gaps. Where the law's provisions were clear, enforcement was spotty, and few bylaws existed to help officials operationalize the law. Fines were too small to serve as a meaningful deterrent to corruption.

### *Drug Prices*

30. Drug prices were not regulated. Prices were subject to mark-ups by wholesalers and pharmacists, and varied considerably from pharmacy to pharmacy. Gross drug margins were very high, about 14% on average at the wholesaler level and 27% on average at the retail level. The DPL analysis had provided the following data on average drug mark-ups, which varied depending upon the price of the drug (Table 2):

Table 2: Margins on Pharmaceuticals in Bastania

	<b>Importer and wholesale margin</b>	<b>Retail margin</b>
<b>Most expensive drugs</b>	8%	15%
	10%	20%
	15%	30%
<b>Least expensive drugs</b>	18%	33%

31. Not surprisingly, pharmaceuticals comprised a major component of growing health expenditures; pharmaceutical expenditures as a percent of total health expenditures jumped from 8.3% in 1992 to 13.5% in 1997 (Table 3). Out-of-pocket spending on drugs was also increasing at a high rate.

Table 3: Pharmaceutical Expenditures in Bastania and Neighboring Countries, 1997.

	<b>Bastania</b>	<b>Country A</b>	<b>Country B</b>	<b>Country C</b>	<b>Country D</b>	<b>Country E</b>
<b>Total pharmaceutical expenditure (USD)</b>	130	93	180	39	450	65-80
<b>Market growth rate, local currency</b>	Not available	>10%	10-15%	15%	20%	10%
<b>Total drug spending, including out-of-pocket payments, as a % of health care expenditures</b>	8-15%	23-32%	12.4%	14.9%	14.8%	30%
<b>Drug expenditures per capita, USD</b>	65	26.5	<50	65	60	33-40

### **Decision Points Along the Pharmaceutical Supply Chain**

32. Kachanik directed a member of his staff, Mikal Pilichova, to begin investigating the pharmaceutical market to identify possible inefficiencies, lack of capacity, unethical practices, and opportunities for corruption. Pilichova's initial analysis confirmed that, as in most countries, the Bastanian pharmaceutical market was quite complex, translating into a high number of decision points where problems could occur.

*Point #1: Manufacturing and Quality Control*

33. Obtaining a license to sell medications in Bastania required that the drug manufacturer provide a certificate of good manufacturing practices (GMP) for each drug and for each of its factories. GMP is a term used to describe a set of quality assurance-related principles and procedures defined by national law for drug manufacturers to follow, thereby ensuring that the products produced meet quality standards. To obtain a GMP certificate in a given country, a manufacturer has to follow a detailed handbook of process details; for example, the handbook defines the training of personnel, the process documentation requirements, the sign-off points, the design of the building, specifications for air quality and filtration systems to avoid cross-contamination, accurate container labeling processes and checks, and validation methods.

34. Following this detailed protocol is burdensome, complicated and expensive for drug manufacturers. While large multinational manufacturers typically maintain systems to monitor and confirm GMP, smaller drug manufacturers tend to cut corners in order to reduce costs. Companies may be found deficient in their processes for a certain product, or their processes may be GMP compliant in certain factories but not in others.

35. Although GMP was legally defined under Bastanian law, the definition was somewhat loose and open to interpretation. Compounding the problem was that inspectors from the Bastanian General Inspectorate of Business sent to evaluate local factories for GMP compliance were inadequately trained and poorly paid. Because GMP was not appropriately defined or enforced, Pilichova believed that counterfeit, fake or substandard drugs were likely in circulation.

36. Another problem was quality control, which was overseen by two laboratories located in Bastania. One laboratory was attached to the Ministry of Health, and had very little equipment and capacity. The other laboratory was located in the Department of Clinical Pharmacology at Bastania University. As Pilichova told Kachanik, “Limited capacity for quality control makes it even more likely that counterfeit medicines with dangerous components or manufactured at suboptimal doses could be passed along to the public.”

*Point #2: Licensure and Registration*

37. In order to sell a drug in Bastania, two types of licenses were needed: one license for the manufacturer and one license for the particular product. In both processes, Pilichova learned, licensing decisions rested in only a few hands.

38. Regarding manufacturer licensure, manufacturers had to submit documentation to a division in the Ministry of Industry in order to be licensed to sell products in Bastania. One designated ministry official processed the minimal amount of paperwork needed at this step.

39. Regarding product licensure, a commission under the Pharmaceutical Regulatory Bureau was responsible for granting licenses for particular drugs; the process was supposed to confirm a drug's efficacy, safety, labeling, marketing, usage, warning, and prescription requirements. In Bastania, a handful of bureaucrats were responsible for processing the paperwork prior to commission review.

40. "I was told that even though our drug had European Union market registration, it would take over 200 days to register the drug in Bastania," said one manufacturer. "But I'm not sure why – I've heard that other manufacturers experienced a much shorter registration process."

41. Here, Pilichova turned up his first real evidence that corruption did exist: apparently, officials frequently requested "facilitating fees" to process licensing documentation. Typically, larger, multi-national corporations refused risk their reputations by acquiescing to bribery; many preferred not to participate in HIF tenders directly, instead working through importers or distributors. However, importers, local manufacturers and manufacturers located in small countries were willing to pay financial incentives in order to ensure that their licenses were granted.

42. "We understood that a commission would make the decision about our drug licensure, but first our paperwork had to be reviewed by a single person," reported one manufacturer. "That person directly requested money in exchange for processing our paperwork a little faster."

43. Another manufacturer reported a request for a bribe directly from the head of the Pharmaceutical Regulatory Bureau: "He noted that he alone determined the priority in the review process, as well as whose documents would be read with more scrutiny," the manufacturer noted. "For a small fee, he said he would direct his staff to move our files along more quickly. He told me, 'These little facilitating payments are no big deal. This is simply our culture. It has always been this way.'"

44. In other cases profiled in Pilichova's reports, officials seemed to discourage the licensing of international products by causing excessive delays in the process. One international drug manufacturer told Pilichova that his company simply refused to do business in Bastania: "The process is not transparent, standards are poorly defined, and the rules that do exist are applied unequally across manufacturers."

45. Kachanik immediately recognized that, aside from the direct evidence of bribery, the lack of transparency in the licensing decision-making was concerning. For example, Pilichova told him that before a medication was licensed, the manufacturer was required to obtain an expert opinion from a pharmacologist approved by the Ministry of Health. Because Bastania University was the only major institution of higher learning in the country, virtually all of the country's pharmaceutical experts were colleagues in the school's Department of Clinical Pharmacology. Other experts were practicing physicians whose families had financial interests in wholesalers or manufacturers. Others had relatives who were high-ranking political officials. "Expert opinions regarding a drug's

licensure could easily be tainted by economic, political or personal concerns,” worried one manufacturer.

*Point #3: Importation*

46. Pilichova moved on to examine the importation process, a third decision point where inefficiency and corruption could occur. Even when a drug had an import permit granted by the Drug Regulatory Bureau, every batch crossing the border had to be declared via documentation that was submitted to customs authorities responsible for import approval and taxation. Customs officials negotiated the payments of duties and taxes, and determined the timeframe for clearance of goods.

47. “The distributor we used to accompany products across the border told me that the customs official found a reason to delay the clearance of the shipment, even though our paperwork was complete and accurate,” lamented one manufacturer. “I’m not quite sure how or why the shipment was eventually cleared.”

*Point #4: Drug Selection for Reimbursement*

48. Once they cleared customs, drugs could be made available to the public through health facilities and pharmacies. However, this was not enough: manufacturers wanted their products to be listed on the Essential List of Drugs, a listing of drugs that would be reimbursed by the Bastanian health care system. Manufacturers knew that if their products were on the list, they could maximize sales and be assured of a relatively predictable share of the market.

49. The scientific committee that prepared the Essential List of Drugs was independent of the Ministry of Health. However, committee members were appointed by the Minister of Health and the Health Insurance Fund, and thus were politically connected. Pilichova learned that some members owned pharmacies or held financial interests in drug wholesalers or manufacturers, not only in Bastania, but also in neighboring countries that exported drugs to Bastania. Still other members were physicians who conducted clinical research and stood to benefit professionally from the widespread use of a particular drug. Tenure among committee members averaged about 14 months.

50. Other than vague references to “evidence-based medicine,” Pilichova was concerned about the lack of transparency regarding committee decisions. Even the pharmaceutical manufacturers did not understand the selection criteria against which their drugs would be evaluated. Because there were no written guidelines for how drugs won a spot on the Essential List, committee members routinely talked personally to manufacturers about the process.

51. Pilichova told Kachanik that this step would have to be examined carefully prior to designing reforms, because the Essential List had important implications for health expenditures. Often, the drugs listed were newer, higher-priced medications, while lower-priced alternatives or generics were excluded. In some therapeutic drug categories,

numerous alternatives were included without regard to relative cost-effectiveness. “Government officials arguing for rational health expenditures tended to be intimidated by the social status and political clout of the committee’s clinical experts,” he noted. Aside from financial concerns, Pilichova recognized the potential for negative health implications, given that it was unclear how committee members evaluated comparative efficacy criteria.

*Point #5: Procurement*

52. The goal of drug procurement is to enable the public health care system to acquire the right quantity of drugs most cost-effectively from drug suppliers. Functions related to procurement include quantification of need/demand, inventory management, aggregate drug purchasing, public bidding contests, technical analysis of offers, rational allocation of resources, payments for drug products, receipts of drugs purchased, and coordination with quality control activities carried out by drug regulatory agencies. In Bastania, procurement was poorly documented and processed: many process steps were involved, assessment of drug needs was subjective, and contract values were high.

53. After his investigation, Pilichova realized that despite centralization, significant problems still existed in the procurement process. For example, estimation of drugs and quantities needed was not based on a particular methodology; rather, a pharmacy would simply contact the Health Insurance Fund to request a given amount of drugs. Lack of reliable estimates for drug stock requirements generated conditions of alternating over- and under-supply. Inaccurate assessment of drug needs meant that drug budgets could not be set accurately and expenditures were excessive. Few internal controls meant that the HIF did not monitor whether pharmacies and hospitals were giving the procured drug or higher priced alternatives to patients.

54. The processes relating to soliciting wholesaler bids for contracts were also problematic. No one could really explain to Pilichova how bids were advertised – “We just call wholesalers and tell them about the bidding opportunities,” said one official – leading him to suspect that bidding was not advertised widely.

55. With procurement centralized at the Health Insurance Fund level, commission meetings were held to assess bids from drug wholesalers. Pilichova had learned that commission members were sending text messages through cell phones to their preferred bidders outside the rooms. “Once they learn the lowest bid, they send a text message to their preferred bidder,” Pilichova related to Kachanik. “In this way, commission members appear to officially follow protocol, but actually compromise the procurement process.”

56. At other times, wholesalers decided who would bid on which contract. Wholesalers readily admitted to this system. “This is an efficient and fair way for us to share the work,” one wholesaler told Pilichova when questioned about the practice.

*Point #6: Distribution*

57. Unfortunately, Pilichova next learned that the Bastanian drug distribution system did not reliably ensure the timely and safe delivery of appropriate quantities of medications to health facilities and pharmacies.

58. In fact, quite often hospitals and pharmacies did not have needed medications due to breakdowns in the distribution chain. Drug supplies were plundered by port workers or stolen by systematic crime syndicates. Drivers sold off products during transportation. Drugs were diverted due to lack of oversight at the warehouses, and then resold in the informal sector.

59. Pilichova was particularly horrified to learn that 4,000 pounds of expired drugs were being sold out of a warehouse directly to patients. “These drugs were imported and paid for, but never reached the patients,” he told Kachanik. “Now, patients may be taking drugs that have lost their effectiveness.” He also heard that refrigeration units in some warehouses were broken, virtually ensuring that the integrity of certain drugs was compromised.

*Point #7: Prescription*

60. Pilichova was heartened to learn that Bastanian physicians did not, as a rule, accept direct bribes from suppliers in exchange for prescribing certain drugs. However, the relationship between the physicians and the drug manufacturers made Pilichova wonder if the pharmaceutical companies were influencing doctors unduly.

61. Physicians were often given gifts, or reimbursed for travel to medical conferences. “I was so pleased to be able to attend a conference out of the country,” stated one Bastanian doctor from the public sector. “My salary is so low – I could never afford the travel expenses on my own!”

62. Some doctors were offered sales incentives in exchange for favored prescribing. For example, some manufacturers offered financial bonuses to physicians based on the number of prescriptions written. “This seems fair to me,” reported one doctor. “Sales incentives exist in other business transactions – why not this one?”

63. Pharmaceutical companies ran many physicians training and education sessions, but no association or government agency had oversight over the accuracy and content of training materials.

64. Some pharmaceutical company representatives were extremely enthusiastic in touting their products; their strong belief in the efficacy of their products impressed many Bastanian physicians, prompting changes in prescribing behavior. “Some drug representatives are very helpful,” said one doctor. “They even provide me with preprinted prescription forms in order to make prescribing more efficient. I embrace any strategy that will help me practice efficiently, so that I can have time to treat even more patients.”

*Point #8: Pharmacy Drug Supply and Dispensation*

65. Pilichova knew that the point of medication dispensing was the culmination of the entire pharmaceutical value chain – the point at which patients should receive the right drug at the right dose, accompanied by appropriate information. Unfortunately, Pilichova learned that patients were not always receiving the most suitable drug, because the drug dispensing decision was driven by economic self-interest on the part of manufacturers, wholesalers, pharmacists, and even physicians.

66. Officially, pharmacists were encouraged to dispense the cheapest brand of drugs, which had the highest relative reimbursement for the patient (e.g. the lowest copayment). But pharmacists often had a financial interest in dispensing one drug over another alternative. This influence started with the drug manufacturers, who negotiated with wholesalers to supply their products to pharmacies and offered commercial inducements to do so. For example, a manufacturer might offer 50 free packs of a drug to a wholesaler for every 50 packs purchased. Then, the wholesalers would proffer a similar inducement to the pharmacists, offering 30 free packs for every 50 purchased.

67. Manufacturers could also encourage the sale of their products by offering better payment terms. For example, manufacturers would provide drugs but allow wholesalers to delay payment for six months; then, wholesalers would highlight these preferred products in their dealings with pharmacists. Similarly, pharmaceutical company representatives directly influenced pharmacists by giving gifts and offering better terms.

68. Pilichova visited some pharmacies to secretly observe pharmacist dealings with consumers. In many cases, he found that pricing was irrational. “I am confused: the out-of-pocket payment for my drug, which was covered by insurance, is even higher than the full price of another alternatives that was not covered by insurance,” a consumer was overheard telling a pharmacist. In another pharmacy, a customer was told, “I’m so sorry, we are out of stock on the drug your doctor recommended. The good news is that we are offering this alternative, which in fact is much more efficacious. It is a little more money, but I’m sure you won’t mind paying for superior quality.” At other times, Pilichova heard public pharmacists tell customers that they had run out of the subsidized supply of a given drug, and would sell the same product at the market rate.

69. Pharmacists pursued several strategies in order to increase their income. For example, they sold prescription-only drugs over the counter in order to increase sales. Public sector pharmacists also enhanced their salaries by selling drugs to pharmacists in the private sector; health facility staff members were also reselling subsidized drugs, Pilichova learned. Hospitalized patients routinely found that the hospital was out of the drug they needed; family members had to go to a private pharmacy to purchase the drugs – invariably at a higher price.

70. Physicians themselves could dispense as well as prescribe drugs. Physicians were not prohibited from owning pharmacies or from selling drugs out of their offices. Thus,

doctors had a financial incentive to prescribe higher-margin drugs rather than lower-margin drugs, and to over-prescribe certain medications. Furthermore, physicians who worked part-time in the public sector commonly stole drugs for resale in their own private practices, or exchanged date-expired stocks from their practices with up-to-date stocks of drugs and reagents from the public facility.

71. Finally, because drug consumption was not monitored, there was no way to detect fraud on the part of the consumer. For example, pharmacists did not retain the doctor's prescription, meaning that patients could refill prescriptions multiple times and then sell the drugs in the informal sector.

## **Conclusion**

72. After reviewing Pilichova's investigation report, Pilson recognized that the current Bastanian pharmaceutical sector constituted a fiscal risk. He knew that he would have to carefully consider all the core decision points in the pharmaceutical supply chain so that he could determine where and how corruption had been occurring, and design effective anti-corruption strategies to improve transparency, capacity and accountability.

73. Some reforms would have to be specific to one area, while others would have to be broad enough to cover all areas of the pharmaceutical market; all would have to be carefully coordinated. Individual official discretion would have to be reduced. Membership on committees, as well as all decisions made by committee members, would have to be based on objective criteria, and potential for conflict of interest would need to be addressed. A drug's inclusion on the Essential List would have to be based on objective standards of cost and efficacy. Processes to accurately assess medication needs would have to be implemented to ensure accurate drug supply. Systems for drug pricing would have to be considered. Technologies that could help track medications would have to be identified. Laws that allowed discretion, did not mandate adequate checks and balances and transparency, and were silent on issues of conflict of interest would have to be re-written. Pilson picked up the telephone and called Kachanik to discuss potential reforms.

## Discussion Questions

### *Economic and Political Context*

1. Do you think that the primary problem with Bastania's pharmaceutical sector is inefficiency, lack of capacity, unethical behavior or corruption? Why?
2. What are the implications of widespread corruption for a country's financial sustainability, international investment attractiveness, and position in competitive product markets?
3. How can addressing corruption in the pharmaceutical value chain support overall economic reform in Bastania?
4. How can reducing corruption in the pharmaceutical value chain support the goal of closer ties with the European Union?
5. What economic and political factors in Bastania might foster corruption? What factors specific to the health and/or pharmaceutical sectors might make these sectors vulnerable to fraud and corruption?
6. Who is likely to oppose reform of the pharmaceutical market? How can opposition be addressed?
7. Is the Minister of Health likely to be a supporter or an opponent of reform? Why?

### *Organizational Issues*

8. Why might inefficiency and corruption flourish under a highly decentralized system? Why did problems continue even when the centralized Health Insurance Fund was established?
9. How can a system characterized by a high degree of turnover among officials increase the potential for corruption?
10. What are the potential problems associated with the organizational relationship between the Health Insurance Fund and the Ministry of Health? Should this relationship be changed? How?
11. Should a system of both public and private pharmacies be allowed to exist? If so, what systems could be implemented to improve efficiency and decrease corruption in the pharmacies? If not, how should the system be reformed?
12. How can the government formalize relationships with health care institutions in a way that will help track and prevent corruption?

13. How can the pharmacist and physician professional associations be enlisted to help deter corruption?

*Pharmaceutical Supply Chain Decision Points*

14. How do inefficiency and corruption at one point in the pharmaceutical supply chain affect other points? For example, how is procurement made more difficult if the registration and licensing process is inefficient and/or corrupt?
15. Given the different points along the pharmaceutical supply chain outlined in the case, how should they be prioritized for reform?
16. What are the problems with drug quality control in Bastania? How could quality control be improved? What reforms can be suggested to ensure that quality control procedures are efficient and transparent?
17. What are the main problems in the licensing and registration process? How can these problems be addressed?
18. What are the main problems associated with the selection of drugs for reimbursement? What reforms can Bastania pursue to ensure that the drugs on the Essential List are efficacious and cost-effective?
19. What methodologies can be adopted to ensure accurate assessment of drug types and quantities needed? What procurement practices and policies could ensure the availability of drugs?
20. What procurement reforms could be adopted to ensure that high-quality drugs are obtained from reputable wholesalers and manufacturers?
21. What indicators can be used to measure and track the performance and quality of wholesalers?
22. What procurement practices and policies could ensure that drug pricing is not subject to corruption? How can the best prices for drugs be ensured? What is the role of international competitive bidding and reference pricing?
23. What systems can be adopted to ensure that government officials do not unfairly favor certain wholesalers when evaluating bids?
24. What problems exist in the way drugs are stored and distributed in Bastania? What are the goals of a well-managed distribution and storage system? What models can be adopted in Bastania to achieve these goals?

25. What activities and interactions with physicians can drug manufacturers acceptably pursue? What policies can ensure that physicians are not unduly pressured or encouraged to prescribe certain drugs?
26. What reforms can be suggested to correct problems of corruption related to drug dispensing in Bastania?
27. What is the value of separating the prescribing and dispensing functions?

#### *Operational and Legal Reforms*

28. What types of technologies would help Bastanian officials increase efficiency and transparency and reduce corruption?
29. What specific types of legal or operational reforms can be suggested to reduce individual discretion over different points in the pharmaceutical supply chain?
30. How does the general functioning of the legal system affect the ability to address pharmaceutical sector corruption effectively? What stipulations should be covered under the law to make it more specific? How can the government be sure that the laws are operationalized?
31. In a small country, citizens may have overlapping participation in business and medicine, and issues related to conflict of interest can be difficult to manage. What are some solutions that can help mitigate conflict of interest?

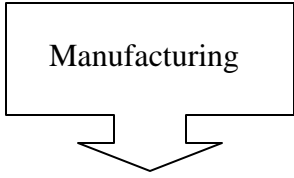
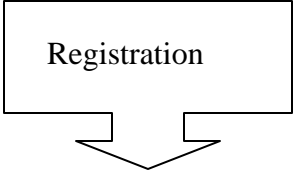
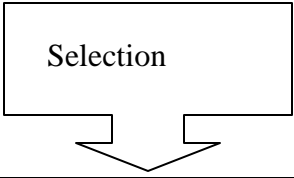
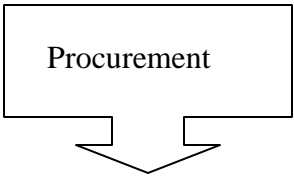
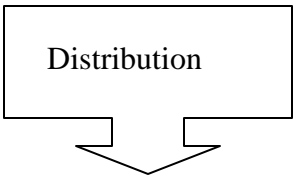
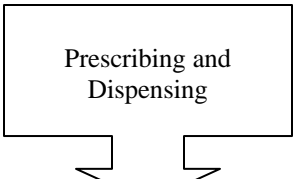
#### *Consumer and Citizen Empowerment*

32. How can the pharmaceutical market and its associated processes be made more transparent to consumers?
33. What is the role of the public in preventing corruption? How can the government empower the public to recognize and report corruption?
34. How can the public be educated about drug quality? Are there certain packaging or other signs that consumers can be taught to identify to spot a counterfeit or substandard drug?
35. Is reform of the pharmaceutical market a good topic for a public relations campaign? Why or why not? If so, what elements and media could be included in the campaign?
36. How is consumer empowerment linked to legal rights and functioning of the legal system?

37. How do professional and industry regulation and disciplinary procedures impact consumer empowerment?

## ANNEX 1

### Key Decision Points and Related Processes in the Drug Sector that may be Vulnerable to Corruption<sup>1</sup>

Decision point	Processes
 <p style="text-align: center;">Manufacturing</p>	<ul style="list-style-type: none"> <li>• Adherence to GMPs<sup>2</sup></li> <li>• Quality management</li> <li>• Packaging and labeling active pharmaceutical ingredients</li> <li>• Master, batch, and laboratory control records</li> <li>• Production and in-process controls</li> <li>• Certificates of analysis</li> <li>• Validation</li> <li>• Tracking complaints and recalls</li> </ul>
 <p style="text-align: center;">Registration</p>	<ul style="list-style-type: none"> <li>• Full registration or abbreviated drug applications</li> <li>• Safety and efficacy</li> <li>• Labeling</li> <li>• Marketing</li> <li>• Indications</li> <li>• Pharmacovigilance and warnings</li> <li>• Batch testing</li> <li>• Reevaluation of older drugs</li> </ul>
 <p style="text-align: center;">Selection</p>	<ul style="list-style-type: none"> <li>• Determine budget</li> <li>• Assess morbidity profile</li> <li>• Determine drug needs to fit morbidity profile</li> <li>• Cost-benefit analysis of drugs</li> <li>• Consistency with WHO (and other evidence-based) criteria</li> <li>• Pricing and reimbursement decisions</li> </ul>
 <p style="text-align: center;">Procurement</p>	<ul style="list-style-type: none"> <li>• Determine model of supply/distribution</li> <li>• Reconcile needs and resources</li> <li>• Develop criteria for tender</li> <li>• Issue tender</li> <li>• Evaluate bids</li> <li>• Award supplier</li> <li>• Determine contract terms</li> <li>• Monitor order</li> <li>• Make payment</li> <li>• Quality assurance</li> </ul>
 <p style="text-align: center;">Distribution</p>	<ul style="list-style-type: none"> <li>• Import approvals</li> <li>• Receive and check drugs with order</li> <li>• Ensure appropriate transportation and delivery to health facilities</li> <li>• Appropriate storage</li> <li>• Good distribution practices and inventory control of drugs</li> <li>• Demand monitoring</li> </ul>
 <p style="text-align: center;">Prescribing and Dispensing</p>	<ul style="list-style-type: none"> <li>• Consulting with health professionals</li> <li>• Inpatient and outpatient care</li> <li>• Dispensing of pharmaceuticals</li> <li>• Adverse drug reaction monitoring</li> <li>• Patient compliance with prescription</li> </ul>

<sup>1</sup> Source: *The Many Faces of Corruption: Tracking Vulnerabilities at the Sector Level*, ed., J. Edgardo Campos and Sanjay Pradhan, Poverty Reduction and Economic Management, World Bank (2007)

<sup>2</sup> Manufacturing processed section adapted from FDA (2000).

## ANNEX 2

### Selected Strategies to Mitigate Corruption in Pharmaceutical Systems<sup>3</sup>

Decision Point	Selected Strategies	Feasibility	Timing
Manufacturing	<ul style="list-style-type: none"> <li>• Ensure legal basis for GMP requirements, including appropriate and credible fines for noncompliance</li> </ul>	High	Short term
	<ul style="list-style-type: none"> <li>• Improve GMP compliance by regular and random inspections</li> </ul>	High	Short term
	<ul style="list-style-type: none"> <li>• Hire a sufficient number of trained and well-paid inspectors</li> </ul>	Medium	Medium/long term
	<ul style="list-style-type: none"> <li>• Develop a rotating schedule for inspectors of manufacturing sites</li> </ul>	High	Short term
	<ul style="list-style-type: none"> <li>• Publicly post a list of compliant manufacturers</li> </ul>	High	Short term
	<ul style="list-style-type: none"> <li>• Publicly name and shame noncompliant manufacturers</li> </ul>	High High	Short term Short term
Registration	<ul style="list-style-type: none"> <li>• Develop transparent, effective, and uniform laws and standards for drug registration</li> </ul>	High	Medium term
	<ul style="list-style-type: none"> <li>• Ensure adequate drug quality control capacity</li> </ul>	High	Medium/long term
	<ul style="list-style-type: none"> <li>• Educate public and professionals to identify unregistered drugs</li> </ul>	Medium	Short term
	<ul style="list-style-type: none"> <li>• Publish drug registration information on the Internet</li> </ul>	High	Short term
	<ul style="list-style-type: none"> <li>• Implement market surveillance and random batch testing</li> </ul>	Medium	Medium term
Selection	<ul style="list-style-type: none"> <li>• Define and publish clear criteria for selection and pricing</li> </ul>	High	Short term
	<ul style="list-style-type: none"> <li>• Make drug selection committee membership publicly available</li> </ul>	High	Short term
	<ul style="list-style-type: none"> <li>• Base drug selection criteria on international standards as set out by WHO</li> </ul>	High	Short term
	<ul style="list-style-type: none"> <li>• Ensure regular reporting of drug selection meetings by the media</li> </ul>	High	Short term
	<ul style="list-style-type: none"> <li>• Publicly post results obtained and decisions made</li> </ul>	Medium	Medium term

<sup>3</sup> Source: *The Many Faces of Corruption: Tracking Vulnerabilities at the Sector Level*, ed., J. Edgardo Campos and Sanjay Pradhan, Poverty Reduction and Economic Management, World Bank (2007). The "feasibility" and "timing" estimates in this table are for Costa Rica.

Procurement	<ul style="list-style-type: none"> <li>• Make procurement procedures transparent, following formal, published procedures throughout the process and using explicit criteria to award contracts</li> <li>• Justify and monitor supplier selection</li> <li>• Adhere strictly to announced closing dates</li> <li>• Keep written records of all bids received</li> <li>• Make results of adjudication available to all participating bidders and the public</li> <li>• Require regular reports on key procurement performance indicators</li> </ul>	<p>Medium</p> <p>High</p> <p>Medium</p> <p>High</p> <p>High</p> <p>High</p>	<p>Medium term</p> <p>Short term</p> <p>Long term</p> <p>Short term</p> <p>Short term</p> <p>Short term</p>
Distribution	<ul style="list-style-type: none"> <li>• Where possible, develop information systems to ensure drugs are allocated, transported, and stored appropriately</li> <li>• Establish regular communication between every level of the system to control inventory movements and deliveries</li> <li>• Secure storage facilities and transport appropriately</li> <li>• Monitor stock in distribution electronically and carefully check delivery orders against inventories of products actually delivered</li> </ul>	<p>High</p> <p>Medium</p> <p>Medium</p> <p>Medium</p>	<p>Medium/long term</p> <p>Medium/long term</p> <p>Medium/long term</p> <p>Long term</p>
Pharmaceutical prescribing and dispensing	<ul style="list-style-type: none"> <li>• Develop and engage professional associations to improve adherence to professional codes of conduct</li> <li>• Use information systems to monitor physician prescription patterns</li> <li>• Impose serious penalties and name and shame for breaches of legal and ethical standards</li> <li>• Regulate industry interaction with prescribers through explicit criteria that limit industry gifts and payments</li> <li>• Require physicians to post industry gifts valued at more than \$25 (Vermont Model) <sup>4</sup></li> <li>• License and inspect pharmacies</li> </ul>	<p>Medium</p> <p>Low</p> <p>High</p> <p>Medium</p> <p>Medium</p> <p>Medium</p>	<p>Long term</p> <p>Medium term</p> <p>Short term</p> <p>Short term</p> <p>Medium term</p> <p>Medium/long term</p>

<sup>4</sup> Under the Pharmaceutical Marketing Gift Disclosure Law 33 V.S.A 2005, the state of Vermont requires the pharmaceutical industry to report recipients of gifts over \$25. Some exceptions apply

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