GOVERNANCE IN BULGARIA'S PHARMACEUTICAL SYSTEM
A SYNTHESIS OF RESEARCH FINDINGS

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1. Introduction

The selection and procurement of pharmaceuticals in health care systems presents a host of governance challenges. Technically sound decisions about the cost-effectiveness of drugs, and objective evaluations of bids, must be made in a political environment fraught with contending pressures from domestic and foreign companies, patients' and physicians' lobbies, and policymakers with strong views. In this report, we undertake an analysis of this sector in Bulgaria.

This study is part of a larger project, **testing program-relevant corruption assessment methodologies.** The USAID E&E Bureau asked the IRIS Center to develop a methodology to assess corruption in selected sectors, particularly at the level of micro-organizations (such as commercial courts, tax administration offices, or schools). The resulting studies are expected to help IRIS experts improve and refine the methodology, and, more importantly, to yield useful results for USAID Missions. The studies incorporate the conceptual framework developed by USAID/EE, focusing on the role of Transparency, Accountability, Prevention, Enforcement and Education (TAPEE) as institutional requirements of integrity – i.e., efficient and effective governance free of corruption (see the Annexes).

This research has two components. The first concerns the central processes of drug selection for the health system, for example the Positive Drug List. The second focuses on procurement of pharmaceuticals by hospitals throughout Bulgaria. The selection procedures are linked ultimately to the procurement of drugs at two levels: by government agencies and hospitals. Competition among pharmaceutical suppliers extends from the very top to the very bottom of the system, cutting across these two levels: seeking Bulgarian Drug Agency (BDA) authorization; competing in other central processes, including selection and wholesale contracting; and seeking deals with hospitals, physicians, pharmacies, and patients.

We used a combination of methods for the two components of the study. The **drug selection component** focuses primarily on the two major selection processes: the Positive Drug List (PDL) and the National Health Insurance Fund (NHIF) Reimbursement List. We also review, more briefly, the selection process involved in the Ministry of Health (MOH) Expensive Drugs List. This research is qualitative in nature, based on interview responses, results of official information requests under the Access to Public Information Act (APIA), and other data and documents according to the TAPEE framework. The interviews included initial "key informant" interviews for background, as well as some 30 structured interviews with officials and firms.

The **procurement component** deals with the purchase of drugs by hospitals. The medicines procured are listed on hospital formularies, which must in turn be selected from the Positive Drug List (unless the hospital operates outside the national health insurance system). This part of the research combined qualitative and quantitative methods. For the qualitative part, we designed focus group discussions and key informant interviews to be conducted by Bulgarian experts. For the quantitative work, we worked with local partners – the International Healthcare and Health Insurance Institute (IHHII) and its survey affiliate, FACT Marketing – to carry out a survey of 148 hospitals (out of 236 medical institutions in Bulgaria) that agreed to participate in the research. The respondents at the hospitals included doctors, nurses, pharmacists, evaluation committee members, hospital directors, and suppliers. We used the survey results, with corroborating evidence, to detect significant levels of corruption, to assign values to the TAPEE factors, and to assess any relationship between these factors and corruption. More information on these methodologies is given in Annex 2.

2. Institutional Setting for Drug Selection and Procurement

Pharmaceuticals comprise a significant portion of healthcare expenditures, especially in the industrial countries. In Bulgaria, they account for some 25-30% of governmental health care expenditure. In turn, the public sector plays a major role in the pharmaceutical market: public expenditure accounts for some 74% of total drug expenditure. The National Health Insurance Fund (NHIF) accounts for 60% of total state expenditure on drugs. The overall market for medicines in Bulgaria was estimated at US $373 million for 2002 (Grace 2003), thus $276 million for government expenditure on drugs, of which $165 was spent by NHIF.

The market for medicinal drugs in Bulgaria reflects the overall transition in economic and healthcare management. State-provided social insurance continues to play the lead role in financing and expenditure oversight of healthcare provision – including pharmaceuticals. Medicines are provided to patients in four main ways: (i) direct state provision of free drugs for defined categories of patients and diseases; (ii) supply of in-patient medicines by hospitals; (iii) reimbursement, in whole or in part, of out-patient prescription drugs by the NHIF; and (iv) private sales, whether of formally registered or grey-market pharmaceuticals. Drugs first undergo market authorization and price-setting procedures – we have analyzed these steps elsewhere (Meagher 2004). Once these two steps have been completed, drug companies can either market drugs through private sales or apply for selection by government for the lists of drugs to be supplied through the public healthcare system (and then bid for sales within that system). This paper concerns the latter pathway.

Central Selection Processes

The *Positive Drug List* designates all drugs considered essential for the health care system, in light of Bulgaria's health profile and needs. All medicines used in state-financed health facilities and programs, or covered in whole or in part by the National Health Insurance system, must be on the Positive List. Somewhat unusually, the PDL contains brand-names, both those justified as having no effective generic equivalent, and those found to be useful on pharmaco-economic grounds. The list is compiled by an independent body, the Commission on the Positive Drug List (CPDL). The Commission operates under a broad mandate to list drugs consistent with the effective implementation of healthcare policy – while leaving it to the NHIF to determine which drugs it can afford to reimburse, in the form of a separate Reimbursement List (see below). The Commission should have 13 members. A supermajority vote of the Commission is required to include a drug on the list.[1] These votes are subject to approval by the Minister of Health.[2]

The *NHIF Reimbursement List* designates a sub-set of drugs on the Positive List – all of them for outpatient use – as those that the National Health Insurance Fund will reimburse, in whole or in part. The process of compiling this list is less transparent – and time-bound – than the Positive List process (PPR 2004). The NHIF covers an increasing portion of all health care system costs,

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[1] Decree 81 of 2003, setting up the Commission, says that it should have a chair and twelve members, and that a quorum of ¾ of members and a vote of ¾ of members present is required for a decision. The CPDL in 2004 operated with a full complement, but in 2003 had only 3 members – all from the Ministry of Health.

[2] According to statistics from the MOH, 87% of proposals for the first PDL (December 2003) were accepted. In the 2005 Positive List there are a total of 2816 products; 336 of them are new products (148 innovative and 188 generics; of the latter, 10 are Bulgarian and 178 imported). For the current list, 201 applications were submitted for 462 International Non-patent Names (INNs). Of these, the commission approved 146 INNs (63 original products and 83 generics).

including those for hospitals (see Meagher 2004). The NHIF used an ad hoc list up until 2004. During that time, drug companies continuously proposed new medicines. As a result, over 50 drugs were added to the list during the first half of 2003, along with eight changes in reimbursement policy during the same period (Grace 2003). Once the first Positive List was adopted in late 2003, comparisons showed that some 280 drugs on the NHIF List were not on the PDL, and so had to be purged from the NHIF List.

In 2004, the NHIF formalized its process of compiling and updating the list.[3] The Fund's rules envision the appointment of an internal commission to handle the key processes such as setting selection criteria and negotiating with suppliers. The NHIF proposed a set reimbursement criteria in early 2004, and these were reviewed by an organ of the Council of Ministers known as the Transparency Committee (TC). At that time, no draft was published (based on the view that the rules were discretionary). However, unofficial copies circulated, and eventually the criteria were incorporated into a formal regulation.[4] Once this regulation was approved, the NHIF could then develop the list, based on the content of previous lists, proposals from the pharmaceutical companies, and the NHIF's own information.

The *Ministry of Health Expensive Drugs List* provides drugs for the treatment of 13 high-priority diseases and conditions, including HIV, cancer, and kidney conditions requiring dialysis. The cost of these drugs is fully covered by the national budget.[5] The applicable regulation deals with the methods of prescribing and dispensing these drugs at the hospitals, but does not define procedures or standards for the selection of drugs on the list. The present list was created by an internal Ministry of Health working group, comprised of experts and administrators appointed by the Minister. Selections of actual drugs to be procured and provided to the hospitals are made on the basis of recommendations by specialists in the relevant fields, as well as the financial limitations imposed by the Ministry's Expensive Drugs budget. Procurements are made at the central level, under the Law on Public Procurement. The Expensive Drugs budget is not reported as a separate component of the MOH budget, but the specific drugs and quantities procured are known. In 2003, the MOH procured an estimated US $60 million in medicines for the Expensive Drugs program.[6]

Procurements by Hospitals

Most public hospitals[7] conduct their own procurement of medicines, though among the first 150 hospitals selected for our survey, 28 did not do their own procurement. The procurement process is usually conducted for each calendar year. A list of the medicines and quantities needed may be drafted by the hospital's chief pharmacist and the hospital director. Or, the hospital may have a special review board created for the purpose of reviewing and approving the list. The list, along with quantities of each medicine, is drafted into tender documents, which are signed by the director and published in the state newspaper and at least one daily newspaper, as well as sent to the public register. (See Annex 4 for a diagram of the procurement process.)

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[3] This selection process runs in parallel with the negotiation of the National Framework Contract (NFC) between NHIF and the Associations of Physicians and Dentists, and the list becomes an annex to the NFC.
[4] Regulation of Conditions and Order for Negotiation of Drugs to be Fully or Partly Reimbursed by NHIF, of August 20, 2004.
[5] The drug list is contained in Regulation no. 23 of 2000, which was updated by Regulation 36 of October 2004. The changes included the addition of 27 INNs (but the budget for the MOH Expensive Drug program was not correspondingly increased).
[6] Estimate from IHHII. While all drugs provided under government auspices are supposed to be on the Positive List, this list pre-dates the PDL and contains several drugs that are not on the PDL.
[7] Public hospitals are owned by a combination of shareholders including the Ministry of Health, other central government departments, and municipalities.

Procurement practices at the hospital level are also shaped by the overall administration and oversight of each hospital. Since the health system reforms of the late 1990s, some health facilities continue under full state control. Hospitals are required to be incorporated; a few are privately owned, while a majority has a mix of state, municipal, and private ownership. They are administered by a manager or board of directors (depending on corporate form), and the latter appoints the doctors and other personnel. Increasingly, the bulk of (formal) hospital revenue comes from NHIF payment for documented treatments according to "clinical pathways" (and the newer "diagnosis-related groups"). NHIF funding to the hospitals is disbursed and controlled by the network of Regional Health Insurance Funds, one per region. Additional oversight is provided by inspectorates at the Ministries of Health and Finance.[8]

Up to 2004, the hospitals typically ran large deficits, which were covered not by the municipalities that owned the largest share of hospitals, but by subsidies from the MOH. Indeed, municipalities and hospitals reported lobbying for these subsidies. Several explanations of the funding shortfalls are possible, including the political imperative for municipalities to keep excess medical facilities running (resulting in a high ratio of hospital beds to population across most of Bulgaria), and waste in hospital operations. This arrangement of ownership and financial control appears to discourage hospitals (and municipalities) from maintaining tight expenditure discipline, including in the procurement area. There have, however, been a few initial attempts by municipalities to exercise stronger oversight (Meagher 2004, Semerdjiev 2003).

Legal and administrative framework

Primary guidance for the procurement of medicines by hospitals originates from the Public Procurement Act (PPA).[9] There are three kinds of procedures: open, limited, and contracting. We deal mainly with open procedures, the most common method used for the purchase of medicines by hospitals.[10] Open procedures require the invitation for participation to be sent to the State Gazette and to the Register of public procurement, and to be advertised in either a local or national newspaper.

Hospitals must appoint an evaluation commission for reviewing the bids. External experts are allowed, as is remuneration of members. The law describes who may *not* be a member of the commission, e.g., someone "connected" in the sense of the Commercial law with bidders.[11] The commission ranks the top three bidders. Each supplier must put up a bond (bank guarantee) as evidence of its financial viability. Proposals are opened in the presence of the hospital's evaluation committee and the supplier, should the supplier choose to be present.

Bidders may appeal decisions within seven days after the decision is announced through the hospital. The courts are supposed to hear the case within one month, but suppliers reported that it can take up to a year for a decision. Under the prevailing law at the time of our research, the procurement would be held up pending resolution of the case. Hospitals complained about this, as they needed the medicines, so the newly-revised PPA allows procurement to continue (but in interviews, suppliers expressed a lack of confidence in the reform).

From the supplier side, the procurement process includes reviewing the tender documents, which must be purchased from the hospital, and gathering an enormous amount of paperwork, much of

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[8] Information provided by Denitsa Sacheva of IHHII.

[9] The Public Procurement Law revision is took effect October 1, 2004. As our surveys were implemented mostly before this date, the research concerns the old law, SG. 43/26, 45/30 Apr 2002.

[10] Of the 148 hospitals studied, hospital directors say the open procedure is the most used (93.8%).

[11] Also excluded are those who participated in the preparation of the tender documents, or are members of hospital management. PPA Article 38.4. This subarticle is not in the new law effective 1 October 2004.

which must be certified or notarized, for each bid. Key informant interviews suggest the process is very time-intensive and tedious, and also something of a gamble – suppliers find the evaluation process to be opaque despite the PPA's rules. Some suppliers complain that the required paperwork is nearly impossible to provide.[12] A hospital may disqualify suppliers if they do not submit all of the required paperwork, but most evaluation committee members said that a hospital will most likely have suppliers submit missing documentation within a set timeframe.

There are a number of formal controls in place, both internal and external, including conflict-of-interest rules, appeal rights, and procurement audits (see below). Also, with the exception of the proposal opening, when the committee and the supplier may be in the same room, all of the communication with the suppliers is required to be in writing. If any bidder's price is extremely low, then a written explanation is required. One clear weakness is the system's inability to keep the tender design and bid selection processes separate, as required by law and good practice. Over half of evaluation committee members interviewed reported having been involved in the tender design process as well. As with some other shortcomings in the system, this one appears to be driven by an insufficiency of qualified people.

Hospital Evaluation Committee

The evaluation committee consists of a lawyer (as required by the PPA), and any or all of the following: a procurement expert (if the hospital has one, or hires one to serve on the committee); the hospital's deputy director (if the hospital has one), sometimes referred to as the financial director; the hospital pharmacist; the hospital's Heads of Department; a doctor; and the Head Nurse. The committee must consist of at least three people, but some hospital evaluation committees have as many as 8 or 10 members. Members must recuse themselves if they have any material involvement in the outcome of the evaluation procedure.

Evaluation is based primarily on the supplier's price, but can also include payment terms and delivery schedules. Supplier's past performance, according to key informant interviews, is not necessarily considered, but could be. According to evaluation committee members, the criteria by which they rank suppliers are as follows, in order of descending importance: Price, quality, payment terms, delivery terms, former experience with the distributor, donations to the hospital, and influence. The committee transmits its written decision to its elected chair, who then passes it to the hospital director for review prior to the hospital offering any contracts.

After procurement

After the procurement process, contracts are offered, and then signed if accepted – sometimes with amendments. Key informant interviews suggest that suppliers win bids and then make contract amendments allowing for higher prices. If a contract is rejected, another supplier, supposedly the next highest ranked supplier, is offered the contract. This was borne out by the evaluation committee members. (Those few suppliers who answered survey questions tended to say that hospitals treat their bids fairly.) Once contracts are signed, hospital pharmacists effectively have a "bank" of medicines from which to draw, placing orders with the contracted suppliers.[13] Hospitals have contractual sanctions at their disposal, but do not "blacklist" suppliers, unless the supplier actually becomes insolvent.

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[12] One example is that *each medicine* must have a *short product characteristic* document (SPC), which is a part of the registration of that medicine. Any change in this document is subject to the Ministry of Health's approval. Each SPC is about 20-25 pages long.

[13] Suppliers complained, in key informant interviews, that hospitals do not always purchase all of a medicine for which they have contracted the supplier. Say, for example, the supplier offers 1000 units of

Political-economic pressures of drug market competition

In this field, as in other dimensions of government where "grand" corruption arises, both politics and profits create strong pressures towards rent-seeking and corrupt behavior. (Annex 5 provides background on the pharmaceutical sector relevant to this point.)

International trends

Pharmaceutical marketing practices have become embedded at several points in medical research and practice. One practice that has elicited increasing concern is pharmaceutical company sponsorship of drug trials, medical journal articles,[14] physician conferences, and other scientific and marketing events which can influence pharmaceutical prescription patterns. For example, a U.S. found that about half of the 44 drug effectiveness studies examined were sponsored by pharmaceutical companies. The company-sponsored studies were eight times less likely to reach unfavorable conclusions – due in part to contractual restrictions on methodologies used, and company control over the release of research findings. Drug producers' influence naturally extends from physicians and pharmaceutical researchers to government agencies charged with vetting and approval of drugs. In this area, worrying findings were reported in a U.S. journalistic investigation of FDA advisory committees. Of 159 meetings of these panels examined between 1998 and 2000, nearly all involved members with financial interests in the subject matter. At half of the meetings, fully one-half of committee members had financial interests in the pharmaceutical products being evaluated (despite ethics regulations aimed at preventing persons with financial interests from participating in such decisions). Many committee members with conflicts of interest had been given legal waivers (Krimsky 2003).[15]

In developing countries (and to some extent the transition countries), the situation is in many ways significantly worse. Clinical trials and cost-effectiveness studies may be unaffordable, and so authorities may rely on studies done elsewhere. Training opportunities for physicians are often so limited that pharmaceutical companies provide essentially the only continuing education that qualified physicians receive (McIntyre 1999). Further, physician salary levels are typically paltry; thus doctors are likely more susceptible to commercial influence. International trade liberalization, which bring important economic benefits overall, is often not matched by effective domestic policy frameworks to ensure that drug expenditures reflect health priorities. In the absence of comprehensive national drug policies, there is little to stop commercial incentives – favoring the sale of expensive innovative drugs, including "me too" products – from crowding out medicines likely to be more cost-effective in developing country circumstances (Chowdhury 1995, McIntyre 1999).

A countervailing influence is the existence of a local pharmaceutical industry. This is more typical of the larger and middle-income developing countries (e.g. Brazil, India) as well as the transition region (Bulgaria, Romania), and less so of the poorest countries (e.g. Malawi). The existence of domestic production provides some pressure – both in the markets and at the political

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medicine x for a certain price, but then "loses" on the deal, because the hospital only buys 10 units over the course of the year.

[14] Efforts have, however, been made in recent years by reputable journals to ensure that full disclosure of pharmaceutical funding is provided when warranted.

[15] In a more recent example, FDA approval of painkillers later shown to increase cardiac risks was supported by a panel of 32 experts, ten of whom had consulted for or received research support from the companies whose products were under review. "Experts and the Drug Industry," *New York Times*, March 4, 2005, p. A 18, col. 1.

level – for greater use of domestic products, which are predominantly low-cost generics.[16] These counter-pressures can bring about greater balance in drug policies, but they also pose their own risks of rent-seeking, policy distortion, and corruption.

The situation in Bulgaria

In Bulgaria, the pressures just discussed combine to create significant risks for the governance of the pharmaceutical system. This is borne out in media reports[17] and in our interview findings in Bulgaria. Foreign firms formed associations to press for lower trade barriers and stronger intellectual property protections, and the relevant diplomatic missions (especially that of the U.S.) got involved. Bulgaria's generic drug producers have lobbied aggressively for favorable market access for themselves. Local firms are said to have greater influence on the Positive List Commission and the Ministry of Health, while the multinationals have found Parliament to be more responsive to their concerns. The run-up to EU accession can be expected to intensify competitive pressures. The Bulgarian producers (now predominantly Actavis [formerly Balkanpharma] and Sopharma) face special pressure because the phase-in of international quality standards is increasing the costs of production and imposing tough scrutiny on remaining production units. Inevitably, domestic producers fear even greater loss of market share at accession. Meanwhile, smuggling and counterfeiting are said to be rife.

Pharmaceutical producers and wholesalers aggressively market their goods. Drug company representatives operate in major Bulgarian cities. The companies use physicians as their representatives, and as in the West, they sponsor medical seminars at resorts. They use city hall and other official venues to promote their goods. The major wholesale distributors in Bulgaria also own (or control) pharmacy chains. This practice carries over from the communist era. Privatization and new starts increased the number of wholesalers to an estimated 300 in 2000, and the number of pharmacies to nearly 3,000 by 2003 (Koulaksazov et al 2003). Still, the private drug sector continues to experience fraudulent practices and business failures, which in turn can affect government healthcare administration (see the box below). Producers often diversify their product outlets by using multiple distributors; exclusive distributorships are offered in return for the wholesalers' promises to get the producers' goods onto the central drug lists and into the hospitals (with no questions asked).

The pressures here have prompted reports in the media, and complaints from the international producers, about unfair competition and corruption. These complaints spike each time a major step is completed in the pharmaceutical selection processes, or a change is instituted. For example, when the Positive List was issued, complaints and lawsuits ensued. When many drugs were dropped from the Reimbursement List because they did not appear on the PDL, the foreign companies pointed out that 90% of the de-listed drugs were imported. As one newspaper article put it: "Foreign medicine importers and manufacturers accused the state of racketeering and of forcefully redistributing the medicine market in favor of Bulgarian producers."[18] These accusations – right or wrong – are symptomatic of Bulgaria's failure to implement a fully transparent and cost-effective financing structure for pharmaceuticals.

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[16] However, in Bulgaria, BDA statistics for 2001-2 showed declining consumption of domestic medicines (IHHII research).

[17] Although we obtained a small amount of English-language material from the Bulgarian media ourselves, by far the bulk of the information we have used comes from a comprehensive media analysis produced by IHHII, and spanning the twelve months beginning June 2003, with a later update (Sacheva 2004).

[18] Andreev, Georgi, "Importers Accused the State of Redistributing the Medicine Market," *Capital Weekly*, no. 2, 17-23 January 2004, http://www.capital.bg/weekly/04-02/16-2.htm

Bulgarian drug sales: shell companies and moral hazard

The media have reported a number of fraudulent competitive practices that throw the system's integrity into question. In one scheme, a group of fictitious distribution companies submitted fraudulent low bids (i.e., bids that could only have produced losses if accepted) in drug tenders. When the bidding was won by legitimate companies, the promoters of the shell companies filed protests with the aim of harassing the winning companies into accepting out-of-court settlements, in order to avoid delays and lost sales (Sacheva 2004).

Additional concerns arise from the economic uncertainties and hazy business-government relations typical of transition For example, Magined, a Bulgarian drug supplier, became insolvent and was found to have evaded over 9 million BGN in VAT. Investigations revealed that Magined owed some 10 million euros to drug manufacturers, and in turn it was owed some 10 million BGN by various healthcare institutions (probably impecunious hospitals) in Bulgaria. The company held an estimated 28% share of government procurement orders for pharmaceuticals when it became insolvent. It had essentially no assets, since it depended entirely on government funding (and, allegedly, high-level official contacts) for its sales, and defrauded its creditors, notably the government (Sacheva 2004). This presents a messy work-out situation in which the government and the producers will have to compete for repayment by an insolvent company and a group of healthcare institutions that are at least cash-poor, and probably insolvent, as well.

Meanwhile, another major Bulgarian drug distributor, Commercial League, is demanding payment of arrears from its client hospitals (Sacheva 2004). Typically, the hospitals lack the means to pay – but their failure to pay poses the risk of insolvency to the over-exposed distributor. In both the Magined and Commercial League cases, the government faces the possible failure and liquidation of some combination of hospitals and major domestic supplier firms – unless government conforms to past practice by offering a bailout. This result would likely go against the long-term public interest, but the short-term pressure to provide a bailout is intense – given the "too-big-to-fail" scenario, and its public fallout. Unlike the first example above, these cases have not been shown to involve fraud or corruption, but there remains the distinct possibility that the companies (Magined in particular) have abused their position as wholesalers of state-financed drugs.

Overall Quality of Governance in Bulgaria

As part of our methodology for the overall project, we take into account existing measures of integrity in the countries studied. In the case of Bulgaria, a rich set of governance surveys and indicators exists. We present a summary of all this information in a table that appears in Annex 1. There, the scores for Bulgaria are compared, where possible, with those for a selection of other transition countries, and to the Eastern Europe and Former Soviet Union (FSU) averages. Following is an overview of the findings:

- Overall governmental quality and economic freedom in Bulgaria rank as average or slightly worse than average by Eastern European standards, but do outperform the FSU averages.
- Bulgaria appears less interventionist on microeconomic matters than most transition countries. However, businesses in Bulgaria are more likely to believe that the formulation of laws and policies are influenced by corruption and that state officials face little accountability for rules violations.
- Two widely-used corruption indices indicate that the extent of corruption in Bulgaria is similar to the rest of Eastern Europe. Bulgaria ranks a little better that the East European average according to the Kaufman, Kray, and Mastruzzi measure, but Transparency International's measure indicates that corruption is perceived to be at a slightly lower level

than the Eastern European average. Neither difference is significant. A high percentage of firms in Bulgaria report that corruption is a moderate or major obstacle to their operation and growth. These obstacles imposed substantial costs on the business community.

- Additional evidence of the extent of corruption in Bulgaria can be gleaned from measures of the informal economy, which is generally considered to be positively correlated with the prevalence of corruption. Bulgaria appears to have a large informal economy for a transition economy in comparison to the Eastern Europe average.
- As to the prevalence of different types of corruption in Bulgaria, administrative corruption does not appear to be particularly noteworthy. Firms in Bulgaria seem to pay an above-average percentage of contract value in bribes to secure a government contract, but such bribes are a small proportion of the total bribes paid by Bulgarian businesses.
- Informal payments in the health sector do not appear to be particularly frequent in Bulgaria, although we have only two countries for comparison. There is also limited evidence indicating that such payments, while infrequent, may be significant in size. Within the Bulgarian health system, according to Lewis (2000), such informal payments are primarily directed towards physicians, with payments to procure drugs placing a distant second.

3. Outcomes

We now turn to a review of key results that the Bulgarian pharmaceutical system yields as a result of its institutional set-up, policies, and practices. We are concerned with such issues as appropriate drug choices and procurements, whether prices are in line with the regional market, the integrity of the procedures in practice, and the prevalence of conflicts of interest and corruption.

Appropriate Drug Selections

We evaluate drug choices generally on the basis of the "essential drugs" concept developed by the WHO as a component of primary healthcare (McIntyre 1999). An essential drug must be:

- clinically proven to be safe and effective,
- available in a stable and easily managed form,
- made with only one active ingredient unless a compelling reason exists to do otherwise,
- designed to meet clearly defined healthcare needs, and
- appropriate for varied local conditions.

A test of the appropriateness of an essential drugs list would be its conformity with these principles, embodied in the WHO Model List of Essential Drugs (see the box below). In the case of Bulgaria, we have compared the three government lists (NHIF, Ministry of Health and Positive Drug List) to the WHO list, keeping in mind the different purposes of the lists.[19]

To be clear about our objective in this discussion, it is not to second-guess policy decisions made in good faith. Rather, it is to highlight choices that are seemingly irrational or inefficient – like statistical outliers. The presence of such decisions would lead us to expect some distortions in the drug selection process that may suggest the presence of corruption. We would not expect this analysis to prove the existence of particular corrupt acts, nor of corruption more generally. Many of the drug selections are clearly justified in light of rational drug policy – but others are not. Problematic choices fit into two categories: under-inclusion and over-inclusion.

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[19] These comparisons were done by Judith Fisher of the University of Toronto School of Pharmacy. This section of the paper is based on her analysis. (See the Annex for a description of the methodology.)

WHO: Essential Drugs

The WHO Essential Drug Program was launched in 1977 as one of the pillars of the WHO's Primary Health Care Strategy. The Essential Medicines List is a list of drugs deemed to be necessary for the safe and effective treatment of the majority of communicable and non-communicable diseases that affect the world's population. The drugs on the list are selected with due regard to disease prevalence, evidence regarding safety and efficacy and comparative cost-effectiveness. The list is intended to serve as a model (in otherwords, a baseline) for individual countries to adapt to their particular needs. An expert panel reviews the list every two years, incorporating therapeutic advances and understanding, and changes in disease prevalence. The first Essential Drug List included 208 drugs, whereas the 13th list, published in 2003, lists 316 individual medicines including 12 antiretroviral agents.

Given the differing epidemiological profiles of countries around the world, deviations from the WHO list may be justified but need to be explained openly and transparently.. A number of past studies have compared drug purchases in developing countries to the WHO or other formularies. For example, a study in Bangladesh estimated that some 70% of annual drug sales were for preparations deemed therapeutically useless by drug approval authorities in the UK and U.S. Another study compared medications sold in developing countries to the WHO list. Only 16% of drugs sold by the 20 largest European pharmaceutical companies in 49 countries were deemed essential (Patel 1983 and Hartog 1993 studies, cited in McIntyre 1999).

Cases of *under-inclusion* involve the selection of newer (usually more expensive) pharmaceutical agents to the exclusion of older agents that remain cost-effective in many situations (and continue to be recommended by the WHO). An example of this is the inclusion in the PDL of the antibiotics clarithromycin and azithromycin but not erythromycin – a longstanding first-line treatment for pneumonia and pathogens that cause other respiratory infections and some soft tissue infections. Normally, one would expect an essential drug list to also include erythromycin, the prototype medicine of its class (macrolide antibiotics), since it remains a useful, relatively low-cost, and cost-effective antibacterial agent. Another questioned choice is the inclusion of medium and high potency cortico-steroids but not the (relatively inexpensive) compounds indicated for first-line treatment. Such choices seem to cut against the policy objective of cost-effectiveness. (The NHIF Reimbursement List reflects some of these same choices.)

Cases of *over-inclusion* involve two scenarios. One is the selection of compounds that are deemed by international medical opinion to have only questionable efficacy (and do not appear on the WHO list). The other is listing a large number of alternative compounds within a given therapeutic drug category. Examples include the appearance on the PDL (and in some instances the NHIF list) of multiple brands of statins (5 of them), ACE inhibitors (7 of them)[20], enalapril, and others. The NHIF list also includes 8 brands of ibuprofen (and includes some medicines that can only be administered in a hospital setting, contrary to its outpatient function).

The inclusion of alternatives is often sensible in light of differences in response across patients. However, a long list of alternatives (even if ranked by pharmaco-economic criteria) seems to defeat the policy objectives of having a *selection* process to begin with – i.e. limiting choices so as to provide essential drugs cost-effectively.[21] Where multiple brand names can be listed, the

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[20] Angiotensin converting enzyme inhibitors, for treatment of hypertension and post-myocardial infarction.

[21] A crude numerical comparison of the PDL with the WHO list seems to support the over-inclusion thesis: the WHO lists just over 300 compounds, while the PDL contains 667 of them, with a total of nearly 2500 brand names listed. This represents 87% of those drugs for which applications were submitted (some of these were admitted after applicants appealed an initial rejection). Andreev, Georgi, "Bulgaria Confirms

system appears insufficiently disciplined. It practically *invites* lobbying by pharmaceutical interests, especially since the PDL and the NHIF list essentially "license" the sale of a drug within the publicly-funded healthcare system.

Setting of Prices in Selection Process

Governments globally are dealing with rising costs of pharmaceutical expenditure and typically have regulations in this area (e.g. reference pricing systems (Germany), international comparisons (Canada), caps on profits (United Kingdom)). The Bulgarian media placed major emphasis on drug costs in 2003-4, with most stories reporting that Bulgarians paid higher prices for medicines than patients in several West European countries, notably Germany.

At the same time, there were many media reports about budget shortfalls at NHIF and MOH, caused by large increases in drug expenditures (a staggering 180% over 4 years), and the consequent attempts by those agencies to put downward pressure on drug prices (Sacheva 2004). With funds running low due to inadequate budgeting and forecasting, NHIF in mid-2003 withdrew over 48 million BGN from its large reserve fund (kept at the central bank as part of the state fiscal reserve), in addition to tapping its emergency reserves.[22] Adding to this fiscal complexity, the NHIF in mid-2004 reported that "unregulated payments to the health care system" equaled the total annual healthcare budget of 1.6 billion BGN for that year.[23]

Is Bulgaria making cost-effective choices, and controlling its drug costs? An important dimension of this is the prices paid per unit of medicine. Our team carried out some international price comparisons in order to test whether prices were within a reasonable range.[24] We compared NHIF reimbursement prices for this year with those of five out of the eight countries for which NHIF is required to conduct its own comparisons in order to set prices.[25] NHIF sets a reference price based on the lowest acceptable bid from applicant firms, and then determines the maximum reimbursement by selecting the lower of (a) the reimbursement price used by NHIF in the previous year or (b) the average price covered by public health funds in eight comparator countries. The IHHII research team had chosen a set of 20 INNs to use for both the international comparison and our parallel study of procurement prices paid by Bulgarian hospitals. Of these, seven appeared on lists in both Bulgaria and other countries in our group of five. This sample is not scientific but indicative.

We took the average differentials in the prices of those drugs in our sample that appeared on the NHIF list and equivalent lists in our comparator countries. Drugs in Poland and Slovenia appear quite expensive in comparison to Bulgaria – although these differences would diminish if we accounted for higher per capital incomes in those countries. The others are quite cheap in comparison to Bulgaria (cheaper still if per capita income were taken into account). These results

List of Medicines to be Paid by Public Funds," *Capital Weekly*, no. 49, 6-12 December, 2003, www.capital.bg/weekly/03-49/3-49.htm
[22] Andreev, Georgi, "NHIF Unblocks Reserve Funds," *Capital Weekly*, no. 35, Aug. 30 – Sept. 5, 2003, www.capital.bg/weekly/ . This was a replay of 2002, when NHIF overran its budget for free or partially free medications by nearly 100% (BGN 240 million, against BGN 131 billion budgeted, Sacheva 2004).
[23] Dessislava Nikolova, "Supplementary Exam for Health Care Reform in Bulgaria," Capital Weekly, no. 35, 2004, www.capital.bg/weekly/
[24] These comparisons were done by Ms. Mina Popova, consultant to IHHII.
[25] The five countries are: the Czech Republic, Poland, Romania, Slovakia, and Slovenia (the others being Greece, Latvia, and Hungary). They were selected among the eight because of the similarity of their healthcare systems to that of Bulgaria.

are consistent with the view that Bulgaria pays relatively high prices for drugs.[26] A summary of findings from this price comparison appears in Table 1 below.

We also looked at price differences within Bulgaria, between the NHIF lists of 2004 and 2005. The 2005 list was the first one compiled using new standards and procedures developed in 2004. Of the 17 products that appear on both lists (name brands within the seven INNs mentioned above), nine stayed the same in price, one (an imported drug) increased in price (by 5.5%), and seven saw reductions – by an average of 29%. Of the latter group of seven drugs, six were produced by Bulgarian firms. This suggests that the new procedures for the NHIF list are constraining prices. But only the prices of domestic products show signs of being limited – and there is little evidence that Bulgaria is controlling overall drug expenditures more effectively than in prior years.

Table 1. International Price Comparison

Comparison country (number of name brand products)	Average price differential vis-à-vis Bulgaria
Czech Republic (7)	- 23%
Poland (11)	+ 56.6%
Romania (7)	- 78.5%
Slovakia (9)	- 8%
Slovenia (5)	+ 113.6%

Governance of Selection Processes

Here, we seek to answer the question: What evidence is there of efficiency, professionalism, and integrity – or the lack of them – in the selection system? We conduct this analysis separately from our examination of integrity factors, below, which is *institutional* rather than result-oriented.

In Bulgaria, corruption in the healthcare and pharmaceutical systems is often reported and lamented – in the media and in private conversations. In our key informant interviews, those outside the selection processes frequently cited corruption or at least inefficiency as a major cause of concern. Our structured interviews of officials and firms were less candid. We posed questions about the integrity of selection decisions from several angles, including kinds of contacts between firms and selection officials, extent of political influence exercised in the process, persuasion tactics used by companies, and compliance with anti-bribery rules and sanctions. As appropriate, the interviewers followed up these questions by probing about the existence of corruption. Officials generally denied that there was corruption, although a few said that they were not certain how clean some of the processes (other than their own) were. Firms were open about informal meetings with officials, and expressed general concern about some processes (NHIF and MOH selections), but did not admit direct knowledge of corruption.

The media leveled a host of accusations against the NHIF and the MOH in 2003-4. Official inquiries have been conducted in some of these cases, including investigations by the Parliamentary Commission against Corruption.[27] One of the most sensational allegations was that the then-Minister of Health served as representative for a foreign drug company in private pharmaceutical deals. Another report suggested that NHIF officials helped arrange exclusive distributorships for particular imported drugs. According to the report, these officials essentially

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[26] This perception is no doubt compounded by the relatively high VAT applied (20%), and margins chargeable by wholesalers (7-12%) and pharmacies (20-33%), before the product reaches the consumer.

[27] While this may be taken as evidence that there is indeed reason to suspect corruption, it is also clear that the bar to politically-motivated corruption charges by parliamentarians is quite low in Bulgaria. MPs have, for example, made statements in the press that increased expenditures on drugs by NHIF and MOH indicated corruption (Sacheva 2004).

promised the producers slots on the "free" list (i.e. the drugs reimbursed 100% by NHIF) in return for their agreeing to the exclusive arrangements. In a third case, the ex-director of NHIF alleged that a Bulgarian drug company and the plurality party in parliament colluded to secure his dismissal. After his departure, according to the report, the value of new tenders won by that company increased by about 60 percent.

Lastly, a bid protest by the drug supplier Commercial League-National Pharma Center devolved into corruption accusations against the Ministry of Health early in 2005. The MOH justified its decision to disqualify the firm's bid – to supply drugs for the Expensive Drugs program – due to the omission of required documentation. Commercial League sued and won an injunction on implementation of the contract. It then released information on its investigation of the firm that won the tender, stating that the company had received its supplier license only a few weeks before the bidding – with the implication that it was a politically-connected shell company (Sacheva 2004, 2005).

These reports, of course, do not amount to proof of the alleged behavior. They do, however, fit with other patterns of corruption that have been established or admitted, and those cited in some of our interviews. For example, the Minister of Health argued for a health insurance reform that would require larger co-payments – reasoning (among other things) that this would help reduce corruption in the system, including side payments to physicians.[28] Also, in the first three quarters of 2003, nine MOH drug tenders were the subject of lawsuits – consistent with media reports that distributors reached private agreements to fix a high floor price for sale of these drugs to the Ministry (Sacheva 2004). Some concerns are based on the government's own oversight reports. The Bulgarian media reported in 2003 that an audit of the NHIF expenditures in 2002 turned up irregularities – including a significant proportion of expenditures made without proper documentation, and nearly one-quarter of total drug expenditures directed to companies under four contracts that were not tendered, as they should have been, under the Public Procurement Act (Sacheva 2004).[29]

Governance of Procurement Processes at Hospitals

In our research on procurement of drugs at Bulgarian hospitals, we asked about management practices that have a clear link to the likelihood of corruption. These issues came up in surveys, key informant interviews, and focus groups.

Procurement rules and procedures

In the hospital surveys, most respondents state that proper procedure is being followed in procuring pharmaceuticals. For instance, no hospital directors admit to signing a contract with a bidder who failed to provide all necessary tender documents (almost all denied there was any bribery as well, see below). There are a few exceptions. Seven of 88 hospital directors and

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[28] Dessislava Nikolova, "Additional Health Service Payments to Stop Bribe Practice in Bulgaria," Capital Weekly, no. 35, 2004, www.capital.bg/weekly/ . (Such a strategy is very unlikely to mitigate potential corruption hazards.)

[29] The next audit also turned up problems, including weaknesses in the financial and managerial control of NHIF activities, raising the concern that the documentation used by NHIF allowed physicians to report activities that they did not actually perform and permitted hospitals to take double payment for services (i.e. from patients and from NHIF).

evaluation committee members at thirty-two hospitals (of 126) admit to using improper methods to rank bidders.[30]

Also, data from our self-administered surveys of hospital directors provide some evidence (though slim) that amendments are frequently made and primarily for the purpose of changing the price of medicines (see Table 2 below). These findings were echoed by some suppliers. In one of the focus groups, a nurse stated that the original bid and contract price is not the actual price paid by the hospital. She stated that there can be a private agreement between hospital management and the supplier to obtain a contract amendment after the procurement is complete, which raises the price. Key informants said that suppliers change prices frequently throughout the contract year.

Table 2. Contract Amendments

Medicines:	**Metoclopramide**	**Ciprofloxacin**	**Diazepam**	**Pentoxyfilline**	**Amikacin**
# of hospitals reporting that they procured this medicine in 2003 (%)	61 (67.8%)	109 (97.3%)	101 (93.5%)	84 (80.8%)	99 (90.8%)
# of hospitals reporting there were annexes made to the contract affecting the price of the medicine (%)	9 of 54 (16.7%)	10 of 84 (11.9%)	9 of 80 (11.3%)	8 of 67 (11.9%)	9 of 77 (11.7%)
# of annexes usually completed for each contract (according to # hospitals reporting)	7 hospitals: 1 annex 2 hospitals: 2	12 hospitals: 1 annex 3 hospitals: 2	12 hospitals: 1 annex 2 hospitals: 2	12 hospitals: 1 annex 2 hospitals: 2	15 hospitals: 1 annex 2 hospitals: 3
Purpose of the annex, where possible answers were: Change of price Change of delivery time Change of payment time Replacement of the medicine Other	12 said price 2 said payment time	21 said price 3 said payment time 2 said 'other'	17 said price 1 said delivery time 2 said payment time 2 said 'other'	16 said price 1 said payment time 1 said medicine replacement 1 said 'other'	19 said price 2 said payment time 2 said 'other'

In key informant interviews, suppliers stated that the required documentation is excessive and that hospitals have the right, according to the Public Procurement Act, to add requirements, making the proposal process exceedingly difficult (the supplier survey did not yield clear results on this point). Suppliers generally agreed that the hospital director plays the key role in procurement. One informant stated "If the Director is changed, all the major players are changed as well." This supplier also said that in most cases, the "major participants have an early agreement with the Director … [and that] the game is over before it begins." Some focus group participants also believe that the procurement process is rigged and the "winner" determined before the competition begins, but none could present any cases or evidence of this (one said that a contract had been given to another supplier due to a personal relationship with the hospital's director).

Donations of medicines and the potential link to contracts

Suppliers and pharmaceutical manufacturers' representatives visit hospitals, often leaving samples or donations of medicines (a practice that appears to be common world-wide). Such

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[30] The adherence to ranking protocol noted by hospital directors appears to have some significant variation (at the 10 percent level) by district. Six hospital directors also failed to include a lawyer on the list of persons who attend the evaluation committee meetings.

donations could have an effect on the medicines doctors select for patients, and could have an effect on the annual list of medicines to be purchased. Focus group participants raised concern about them, though they generally think that manufacturers and suppliers should give donations, since they profit from their relationships with hospitals. Doubts arose with regard to what is termed "requital" of companies by hospital staff with managerial authority. Some participants stated that there are cases of "open lobbying" for one manufacturer over another.[31] In the survey, it turned out that hospital personnel who are likely to know more about both donations and the medicine procurement process are less likely to believe that donations influence procurement. (See Table 3 below for responses to this question: "What is the influence of the drug donations on procurement?")

Table 3. Influence of drug donations on procurement

Amount of influence (%)	none	a little	some	a lot	enormous
Doctors	21.2	36.8	29.2	9.5	3.3
Nurses	26.8	30.3	28.9	10.7	3.3
Pharmacists	59.4	26.1	11.6	0.0	2.9

Ethics and relationships

This area yielded some of the more interesting findings from the focus groups. The relationships are said to be of a "permanent" nature," of professional importance and at the same time somewhat embarrassing." The channels through which communication flows are:

- Information material meant for doctors about new pharmaceutical products,
- Visits from trade representatives with new products aimed at hospital staff, and
- Seminars and conferences, arranged by pharmaceutical manufacturers, whose goal is also to present new medicines.

Many, or perhaps most, of the medical specialties hold annual national meetings, frequently sponsored by pharmaceutical manufacturers. This financial support is the only practical way for hospital physicians to participate in such events. Focus group participants stated that while on the one hand attendance at such events is necessary for continued qualification as physicians, the support from manufacturers generates a painful sense of dependence. Further discussion within the groups elicited comments that hospital managerial personnel receive even greater benefits (like trips abroad). These comments led to similar questions in the survey instruments, which were put to directors and doctors. Doctors attended training abroad in larger numbers than directors, but less in percentage terms. These data support the notion that hospital managers receive trips abroad as "perks," but do not as such confirm a "dependency" between hospital management and manufacturers.

Focus groups with doctors, nurses, pharmacists, and patients included hints that some *doctors may over-prescribe medicine* that they then keep for their own private use (e.g., to sell to private practice patients).[32] Such over-prescribing would come out of the hospital's medicine procurement budget by way of the hospital pharmacy. We do not attempt to measure this potential problem, though the surveys ask respondents if they believe doctors partake in this practice. Doctors reported that this never happens (87%), though 11% say it rarely happens.

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[31] One pharmacist explained an instance where a physician suggested a medicine, but could not show just cause for his opinion. The pharmacist went on to say "He [the physician] had not prepared properly, perhaps he had not prepared the other colleagues properly, either ...."
[32] The practice was described by a pharmacist, who said a physician prescribed a higher than necessary dose of a particular medicine, gave the patient the normal dose, and kept the remainder.

Nurses are in close agreement with the doctors. Fewer than 2% of both nurses and doctors say doctors "sometimes" keep some of the prescribed medicines.

Corruption in Hospital Procurements

Our research affirmed the presence of some of the same informal and corrupt practices documented in other transition and developing countries, such as gratuities given by patients to doctors and hospital staff. Focus groups, for example, discussed patients' providing "gifts" or "donations" in order to get scheduled for surgery or to get care sooner, or paying doctors or "authorized" hospital staff to get treatment or to get medicine that they are otherwise told is unavailable. These payments may be used to cover legitimate hospital expenses, or they may be used for private gain. Generally, nurses are go-betweens and quietly and privately make the "process" known to patients. In the survey, doctors were asked how many doctors in their hospital request informal payments from patients – to which 42% responded that none do, 27% very few, and the rest (12%) some, most or all do so. Asked the same question, 44% of nurses said none and 36% said very few, while the rest said some or all do (19%). Little was said or known in the focus groups about corruption with respect to medicine procurement.

Quantitative measurement of corruption in medicine procurement

Collecting quantitative data on corruption is always a challenge. The parties to corruption are often unwilling to be candid in their statements about their experiences, perceptions can be founded on conjecture and rumor, and other indicators cannot confidently be interpreted as evidence of corruption. The approach we attempted was to collect data in several different ways, and to cross check. People's reports on their own experiences are only indicative – reporting a corruption experience is an uncertain consequence of someone having the corrupt experience.

Overall measure of corruption by hospital: We collected data in four different ways: suppliers' reports on corruption, doctors' and nurses' reports on corruption, audit reports, and procurement prices.[33] In the survey, evaluation committee members were asked how often fellow members of their committee, their hospital's director, and their hospital at large received informal payments from drug distributors. Pharmacists, doctors, and nurses were asked the same question in their surveys. No hospital directors or pharmacists said that an evaluation committee at their hospital had accepted such a payment in the last year; only one evaluation committee member was willing to admit that someone on their committee had accepted a bribe. (They were also asked to gauge the influence of drug donations on procurement).

The responses from these four groups were aggregated into a measure of corruption perception. The maximum value for each respondent was calculated across his or her responses on the relevant questions. This value was then averaged across all four types of respondent to create a hospital-level measure.[34] As constructed, the perceived level of corruption varies significantly (at the 5 percent level) between types of locality, with greater prevalence at hospitals in urban areas.

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[33] The procurement price data turned out to be unreliable due to variations in package sizes. The supplier survey also proved to be a problem. We received information from only 6 of 44 suppliers, and this information was itself incomplete – only 2 answered more than 20% of the questions about hospitals.

[34] This measure was constructed for 148 hospitals in Bulgaria. For the vast majority of these hospitals, save three, it was constructed from the answers of multiple respondents. Five hospitals had two respondents per measure; six hospitals had three respondents; the remainder (135) had four respondents or more.

There is weaker evidence (at the 10 percent level) of significant variation in perceived corruption between the seven hospital types, but no evidence for such variation between districts.[35]

Corruption variable—doctors and nurses only: We constructed another corruption measure based on survey responses by doctors and nurses to questions about informal payments. We reasoned that this narrower measure would be more accurate than the broader one. Compared to suppliers, doctors and nurses are less likely to be aware of improprieties in procurement, but perhaps more likely to talk candidly about them. This tradeoff is a fundamental one in corruption studies: those most likely to know are often also the most likely to be reticent, hence the analyst has to strike a compromise between a respondent's knowledge and candor. Doctors and nurses were asked: "In your opinion, how often do the following receive informal payments or expensive gifts from distributors?...Evaluation committee members? Hospital directors? The hospital?" The answers were on a scale of 1 to 5 (Never-Rarely-Sometimes-Often-Always). They were also asked about the influence of the drug donations on procurement (see above).

Here we used a procedure similar to the overall measure discussed above. For each respondent we calculated the highest numerical answer to the four questions. Then we took the average (of these maximal responses) across all respondents for the hospital. The logic for the first step of the procedure was that the presence of any of these forms of impropriety was evidence of improprieties in procurement that would affect outcomes (*a priori*, a hospital with a director who always took informal payments would have outcomes as bad as a hospital where both the director and the evaluation committee members took informal payments). For the second step, we took the average of all respondents (rather than the maximal response for the hospital), because we had different numbers of respondents in each hospital, and taking the maximal response would have ascribed higher levels of corruption to hospitals with more respondents.[36]

We also took seriously the problem of respondents being reticent about reporting corruption. To address this problem, we implemented a protocol that allowed us to identify reticent respondents.[37] We found 28% of doctors and 38% of nurses to be reticent, and we deleted these observations from the data. We used data from the remaining respondents – further cleaned through a number of consistency checks[38] – to construct the hospital level measures of corruption. The doctor-nurse corruption variable is the one we used in our regression to check the relationship between integrity (TAPEE) factors and corruption (see below).

We did a further cross-check, using audit reports on the hospitals. We found this to be a challenging task. IHHII staff had to travel across Bulgaria to get physical access to the voluminous audit reports. The reports themselves lacked summaries and senior project members

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[35] The hospitals in the sample were of seven types: multi-profiled hospital for active treatment, specialized hospital for active treatment, state psychiatry, regional dispensary, inter-municipal dispensary, specialized hospital for further treatment, and specialized hospital for further treatment and rehabilitation.

[36] The maximum of 5 randomly selected numbers from a distribution is likely to be higher than the maximum of 3 randomly selected numbers from the same distribution.

[37] Respondents were provided with an envelope containing a sheet of paper with two questions, and asked to answer the underlined question (the exact wording is included in the appendix). One of the questions is "Have you ever taken a bribe?" and the other is an innocuous mathematical questions "Does 2+2=4?". Respondents are told that more than 10% of people receive the sheet with the innocuous question underlined. As a result, many respondents may think that saying *yes* is a probabilistic admission of guilt. In fact, every sheet has the mathematical question underlined, and hence everyone should say yes. We found that a significant number of respondents (28% of doctors and 38% of nurses) actually said *no*, and could therefore be classified as reticent respondents.

[38] This basically involves checking if a respondent was more likely to report corruption in a hospital where other respondents were reporting corruption. The data passed this basic consistency check. Nurses appear to agree with other nurses, and doctors agree with other doctors (though less so than nurses).

at IHHII had to read the audit reports to provide us with assessments of the presence of improprieties. Hence, we received an analysis of the audits for only 25 of the 148 hospitals in our study. IHHII graded the audit reports on a 1-5 scale where 1 corresponded to no improprieties and 5 to very serious improprieties. Although these data were correlated with the aggregate corruption measure derived from the doctors and nurses surveys, they provide only limited support to our findings on corruption.
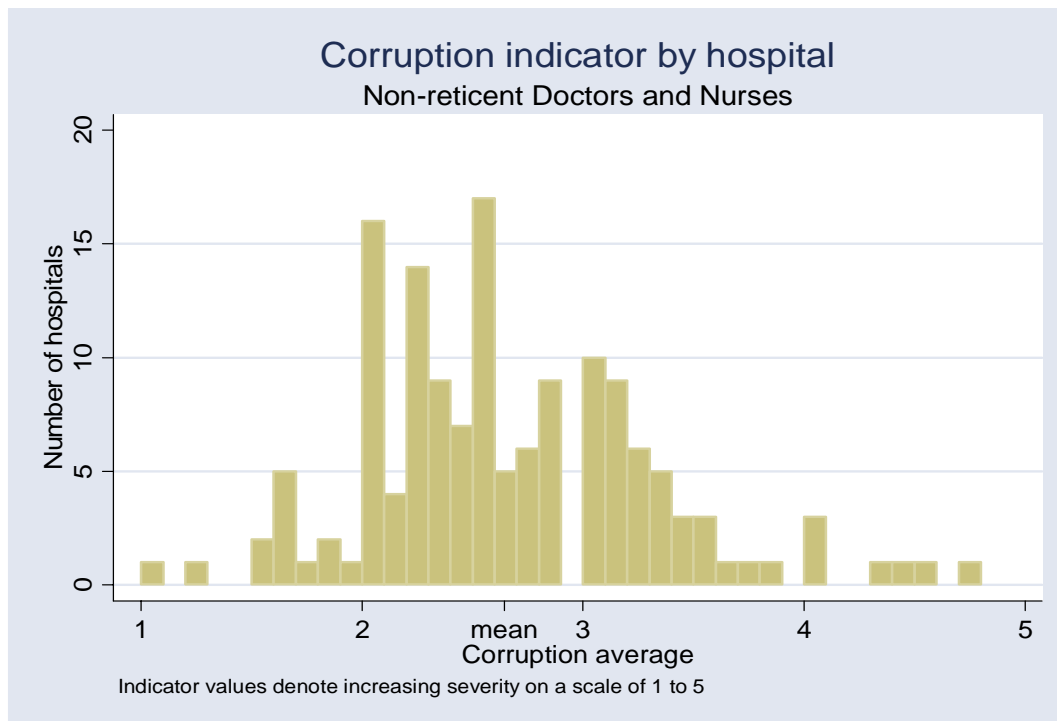
4. Institutional Analysis of Selection and Procurement Systems: Integrity and Vulnerability to Corruption

How do the above findings on pressures and outcomes relate to the institutional arrangements that make up the system? We address this here, using USAID/E&E's analytical framework, TAPEE – transparency, accountability, prevention, enforcement, and education (see the Annexes).

Analysis of Integrity (TAPEE) in Central Drug Selection

First, we apply these factors to the drug selection processes – mainly the PDL and the Reimbursement List, with an additional brief look at the Expensive Drugs List. Our analysis draws mainly on the documents applicable to these procedures (some published, some obtained through APIA requests) and data from key informant interviews. We address specific questions regarding TAPEE factors and rate the results on a four- point scale (poor, average, good, excellent), based on comparisons of Bulgaria's system to "best" practice as set forth in

international standards and the analytical literature.[39]   These ratings are intended to be informative, indicating the likelihood of corruption, without necessarily being conclusive. (Tables of questions and rankings on all the factors, appear below in the discussion of each factor. A detailed presentation appears in Annex 9.)

Transparency

Transparency includes two kinds of openness (see the TAPEE table in the Annex): (i) substantive, referring to the extent to which the content of government policies and procedures is made known to stakeholders; and (ii) procedural, referring to the extent to which official decisions are in fact reached in the open, where the public can follow the proceedings and make its views known. (As part of the study, we made official requests for information on aspects of the pharmaceutical selection system in Bulgaria – see the box below for a description of our experience with such requests.)

Requests for official information

Freedom-of-information legislation, such as Bulgaria's Access to Public Information Act (APIA), is central to transparent governance. We tested the procedures under the APIA as part of this study. Researchers at IHHII made formal APIA requests for some 16 sets of documents and data from the Council of Ministers, the Ministry of Health, the NHIF, and the Agency for State Internal Financial Control (some of these addressed the other component of our study, on hospital procurements of drugs). Officials responded to all of the requests. Not all of the responses were either positive or timely. For example, the NHIF refused to provide its draft regulation on the Reimbursement List, citing the APIA provision that materials used in the preparation of a normative act can be kept secret. This interpretation sounds dubious on its face, but we did not seek an opinion from Bulgarian legal counsel. In any event, the researchers had already obtained a prior draft informally, and soon after the refusal a final version of the regulation was released.

A second problem arose in the request for hospital audit documents. Essentially, they were deemed too voluminous to hand over but researchers were given access, after some delay, to the relevant archives. This result highlights one of the major concerns of our study -- the low quality of official information. In the procurement case, the records were scattered and voluminous as to be very difficult to assemble and summarize. In other cases, records were not complete – for example, not providing any sense of the policy deliberations or the rationale for decisions.

These problems are far from unusual. The Access to Information Program in Bulgaria, in its 2004 report, cited mixed experience with APIA filings. Close to 50% of written requests for information were refused (including a significant number of silent refusals). Two of the cases documented by the Program involved the health system – one involving a request to NHIF for budgets and other financial information on the Regional Health Insurance Funds, and one seeking budgetary and administrative information from a Regional Healthcare Center. Both requests were refused, and the refusals were overturned in the first instance and appeals courts (AIP 2004).

Overall, transparency in drug selection is partial at best. While some key information is either published or obtainable from government, especially in the case of the PDL, there are needless constraints to information flow and public access. Indeed, even in the case of

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[39] In this paper, we draw our "best practices" standards from Cohen et al (2002) and MSH & WHO (1997). Note that these standards are uniform, and do not differentiate between industrial and transition countries.

the PDL, there are some important gaps in available information – e.g. the basis for selection of commission members, detailed criteria for drug selection, limitations on public attendance. As for the other two listing processes, the information gaps are much larger. Thus, only a portion of the overall chain of decisions is subject to public oversight – a cause for concern. Public attendance at sessions and hearings is quite limited, and the written records of these sessions incomplete. Much important information is not published routinely, but made available only after formal requests and waiting periods. Consultation with stakeholders is quite limited.

A concern expressed mainly by the foreign drug companies operating in Bulgaria is that the selection process *as a whole,* starting from application for market authorization and ending with local procurements, creates a series of hurdles that subject companies – especially foreign producers – to discretion and delay. This allegedly enables officials to protect domestic (and favored) producers through selective enforcement. In any event, it appears that Bulgaria's approval and listing processes do not comply with the criteria for establishing drug lists set forth in the EU Transparency Directive (89/105/EEC). A transparent methodology that determines the drugs' necessity for the health needs of the population, and cost-effectiveness, should be uniformly applied.

Table 4. Transparency ratings

Question	*"Best practice" benchmark*[40]	*Bulgaria rating*[41]
1. Are selection guidelines and inclusion/exclusion criteria published and available? Are they clear?	Explicit criteria must be defined and published. Final selection criteria should be based on discussions and acceptance by key prescribers. (See WHO criteria for the selection of essential drugs).	Poor
2. Is the following information about committees and officials making selection decisions published and available: their names, basis of appointment, responsibilities?	Names of selection committee members, their qualifications, and their terms of reference should be public information and listed in the formulary manual and on a government website. The method of appointment should also be clearly stated and publicly available. An organigram which is also publicly available should document each member's background and responsibilities.	Poor
3. How do stakeholders learn about decisions?	Announcement of decisions at public meetings, and an information system that disseminates drug selection criteria and rationales helps to ensure integrity and that, if improprieties take place, they are detectable.	Average
4. Are the drug selection meetings open to the public? Announced in advance? In fact attended and covered by the media?	Public scrutiny of drug selection meetings contributes to transparency and limits unethical practices. Media coverage helps ensure transparency and public knowledge of the processes and decisions.	Poor
5. Are selection processes documented, and are the records publicly available?	Minutes of selection committee meetings should be archived and available to the public	Poor

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[40] *Source:* Cohen, Cercone and Macaya (2002), MSH & WHO (1997).

[41] Ratings for all tables based on rankings developed by Jillian Clare Cohen. See the Annex for the full table.

Accountability

In this context, accountability requires selection decisions to be based on well-accepted standards of scientific evidence and of cost-effectiveness. Decisions need to be explained to stakeholders in these terms. Further, accountability clearly includes systems of internal and external monitoring and controls within the state apparatus, and the duty of public institutions and public officials to account to the public and stakeholders.

The Bulgarian system rates poorly on the accountability factor. Tools of accountability are being put into place, but they are not adequate to the task of ensuring sound, evidence-based selection of drugs, free from improper influences. There is a substantive concern that pharmacoeconomics (PE) and related techniques of drug selection are not well-developed or widely enough understood in Bulgaria (see the box below). The lack of a strong, principled basis for these decisions makes them too vulnerable to subjectivity and manipulation. Worse still, there appear to be comparatively few credible PE analyses that respond directly to Bulgarian conditions. This paucity of data and resources makes it more likely that the pharmaceutical companies will play a larger role in producing these analyses than would be true in the West. There is also the more procedural point that full explanations are not in fact provided, though they are in most cases legally required. If they were provided, Bulgaria would still face the problem that the relevant expertise is not dispersed enough to enable independent, and disinterested, experts to examine them and report to the public.

Pharmacoeconomics

Pharmacoeconomics essentially asks the question: Which choice of pharmaceutical compound is the most cost-effective in a given therapeutic situation? This means asking not only about a drug's effectiveness and cost, but whether, given all the alternatives, its selection represents the best use of the marginal healthcare dollar. Clearly, pharmacoeconomics (PE) is a complex field of policy analysis combining expertise and analytical tools from the domains of healthcare, pharmacology, and economics. There are several standard approaches – cost minimization, cost-effectiveness, cost utility, and cost-benefit analyses (Walley et al. 2004).

Even in the industrial countries, PE is considered to be a field in its infancy, and one that is not universally applied. For example, healthcare systems often have built-in preferences for certain well-established therapies, as well as political imperatives that require a certain level of preference or protection for domestic pharmaceutical producers. Further, the quality and source of PE studies varies. The most credible are those carried out by established researchers and published in reputable peer-reviewed journals. However, studies of this kind are not always available. The pharmaceutical industry frequently steps into the gap and funds PE studies. This, without more, is cause for skepticism, but industry-sponsored studies not uncommonly meet the quality and credibility standards just mentioned. At the same time, the utility of PE analyses depends critically on their being adjusted to local conditions (Walley et al. 2004).

Further, public scrutiny and official oversight are under-developed. Only the PDL process includes any kind of public comment period, and it is extremely limited. More positively, there is provision for official oversight and administrative appeal. However, substantive review is essentially internal to government (i.e. by MOH and Cabinet), and administrative appeals are subject to a deferential standard of procedural review, as in the appeal filed by the international producers concerning the PDL (see the Annexes). Only the external audits appear to be hard-hitting, but given the fact that there have been two adverse audit reports in a row (in 2002-3), it is unclear what impact these have.

Table 5. Accountability ratings

Question	"Best practice" benchmark[42]	Bulgaria rating
1. Are drug selection criteria evidence-based? Are the criteria respected in practice?	The government should have clear guidelines that specify what criteria are being applied for drugs on any public formulary. A transparent methodology that determines the drugs' necessity for the health needs of the population and cost-effectiveness should be uniformly applied. Drug selection must be matched with the pattern of prevalent diseases in country. Government should maintain an information system that monitors drugs once they are in the market.	Poor
2. Are choices in the selection process explained (e.g. inclusion, exclusion, deletion)? Are these explanations publicly available?	Formulary drugs should be listed by generic name. Where possible, generic drugs should be used. The inclusion of a new drug should be based on studies that confirm that the drug is necessary for the health needs of the population and on cost-effectiveness. This is particularly relevant for drugs that are not essential drugs. Deletion of drugs from the national drug formulary should be based on sound evidence that they are inappropriate or not cost-effective for the health needs of the population.	Poor
3. What forms of official oversight of this process exist, in principle and in practice? How stringent are they?	Selections are best made by an independent commission of professionals that is subject to oversight by some combination of the public, the health professions, the courts (administrative law review), by supreme audit agency, and parliament.	Poor
4. In what ways can the public provide input to these processes, e.g. applications, appeals, review and comment on proposed rules?	Open and formal consultations with the public should be institutionalized to ensure that all stakeholder views are taken into account in the drug selection process and that no one group has undue influence. There should be a formalized and regular appeal process for applicants who have their drug submissions rejected, to ensure that standards of drug selection are transparent and fair.	Average

Prevention

Prevention refers to those steps that can be taken to constrain discretion in official decision-making in ways that serve policy goals and avoid corruption. This touches on a range of issues, including the manner of appointing officials, applicable standards and professional qualifications, and the arrangement of official incentives so as to serve policy objectives while minimizing opportunities for self-dealing. In this field particularly, similar attention must be paid to the incentives and opportunities of drug companies and health professionals – given the prevalence, in many countries, of self-dealing by officials and overreaching by the pharmaceutical industry.

Prevention has seen some advances recently, but with glaring omissions and a below-average rating overall. There is widespread concern that the selection commissions are controlled by the Ministry of Health. The selection commissions in some cases purport to be independent, professional bodies, but they in fact are subject to political decisions at the ministry and cabinet levels. As a result, the distinct possibility of undue political influence exists. There is little in the appointment and replacement procedures, even in the cases of the Positive List and Transparency Commissions, to counteract this impression. Also of concern here is the lack of fixed terms or

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[42] *Source:* Cohen, Cercone and Macaya (2002), MSH & WHO (1997).

rotations – e.g., CPDL members can be replaced at any time by a joint MOH-Council of Ministers decision.

Given that the CPDL and others are charged essentially with allocating shares in a lucrative market, there is a strong case to be made that they should be structured like independent regulatory commissions – i.e. outside the executive chain of command, staffed by the full range of needed experts, and with full authority over their implementation of policy. In current practice, some combination of the MOH and the Council of Ministers is given final authority over all decisions. The commissions do not appear to contain the full range of needed expertise, nor a balance of stakeholder representation. Their meetings are infrequent and sometimes ad hoc. Voting rules are specified in most cases, but the meaning of these is doubtful in light of MOH and Council of Ministers approval power.

Provisions on conflict-of-interest disclosure and recusal are not well developed. A comprehensive declaration of assets is rarely required – usually only a declaration of probable conflicts is required, subject to the official's interpretation. Further, we found no evidence of that conflict-of-interest declarations are required to be independently verified. Only civil servant members of these commissions appear to be legally required to sign declarations – the many outside experts that interact with the commissions do not. Last, influence activities are restrained only by vague standards in civil service and voluntary industry codes. (See the box below for a comparative of systems used in the U.S.).

Conflict of interest and drug policy in the U.S.

In the United States, the rules applicable to persons involved in setting pharmaceutical policy are comprehensive and represent a long-term process of refining and extending government ethics rules across federal agencies. Federal employees in general operate under well-established ethics rules and policies, and typically have in-house ethics officers who work with the Office of Government Ethics to ensure sufficient training and compliance. All federal officials in designated grades and sectors (essentially, those involved in policymaking and adjudication) are required to provide a full financial disclosure (of personal and family interests) that is examined and verified. They are also required to observe a one-year "cooling off" period after leaving government service, before accepting any employment that would pose a conflict.

The main U.S. agency involved in drug policy is the Food and Drug Administration (FDA). The FDA has specific rules, applicable to *all employees* that prohibit them from holding financial interests in regulated industries, and from engaging in many outside employments and activities. (In some cases, these are permitted to lower-level employees or upon approval. U.S. Code of Federal Regulations vol. 5, ch. XLV, sec. 5501.) Importantly, the FDA rules recognize the potential conflicts of interest on the part of the many experts engaged in agency consultations and studies. These experts are treated as "special" employees, under a slightly more liberal set of rules. They are required to file conflict-of-interest declarations (not full asset disclosures), using forms that provide guidelines on the identification of potential financial, professional, and personal conflicts of interest (involving the individual and relatives). Financial conflicts of interest result in the expert's exclusion from relevant meetings and assignments – except that waivers are available when the conflicts are deemed not to be substantial, or the need for the expert's services is considered compelling ("Guidance for FDA Advisory Committee Members and Other Special Government Employees on Conflict of Interest 2000," www.fda.gov/oc/advisory/conflictofinterest/waiver.html, but *see* Krimsky 2003).

Thus, partial measures are in place to prevent self-dealing and corruption. In some cases, these provisions may encourage disclosure and thereby prevent corruption. In other cases, the protections may do active harm, providing a "fig leaf" for unseemly dealings.

Table 6. Prevention ratings

Question	"Best practice" benchmark[43]	Bulgaria rating
1. How and by whom are drug selection officials appointed? How long is their tenure?	The drug formulary committee could be the national drug committee or a smaller subcommittee of it. The appointment process should be public and subject to inputs from a number of persons. The committee membership should be rotating or limited in time to reduce likelihood for systematic bias in the decision making process and to limit individuals power and influence in decision making.	Average
2. Do the committees and officials who make selections have the appropriate mix of skills? Are they neutral, or do they represent a balance of stakeholder interests?	The committee should be formally established and composed of professionals with the requisite technical skills, and meet on a regular basis. It should ideally include a clinical pharmacist or pharmacologist, a physician, economist and medical specialists who can prepare and/or review drugs.	Poor
3. What other occupations and activities are selection officials involved in – including active medical practice? Do the rules require the declaration, or at least the avoidance, of possible conflicts-of-interest? Are there limits to officials' contacts with drug companies?	Committee members should disclose all other involvement that may be perceived as conflict of interest. If overlapping responsibilities suggest conflict of interest, the committee member should be compelled to either give up a particular role or resign. Committee members should not have active medical practices, to avoid conflict of interest. Committee members should declare any personal conflicts of interest in writing. These statements should be publicly available.	Poor
4. Are drug-selection procedures conducted regularly, or are there delays between sessions?	Drug selection committee meetings should take place on a set schedule. This will help promote reasonable timelines for decision making and more transparency. There should be minimal delays for market authorization and selection decisions if sufficient information is presented to the government institution.	Average
5. What methods are used to make selections, e.g. unanimous decision, majority vote, choice by individual official? Are decisions vulnerable to political influence – and how is this addressed?	Decision making should be democratic, transparent and subject to formalized voting procedures that rely on majority for outcomes. There are four major methods for quantifying drug needs: consumption (based on historical data), morbidity based, adjusted consumption, and service-level projection. Ideally, a combination of these will be applied to obtain the most accurate drugs for the health needs of the population.	Poor
6. Can interested firms influence the selection process? What methods do they use – e.g. policy arguments, education and promotion, meetings with relevant officials, favors?	There should be clear laws, code of conduct, and regulations governing industry marketing practices. Officials who are involved in drug selection decisions should be barred from meeting with drug company representatives to avoid any potential conflict of interest of influence on decision-making. The government should have a law that explicitly prevents public officials who are members of the drug selection committee from accepting gifts in cash or kind from pharmaceutical companies.	Poor

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[43] *Source:* Cohen, Cercone and Macaya (2002), MSH & WHO (1997).

Enforcement

The question here is whether incentives exist for compliance with the rules, as defined in the above discussions of accountability and prevention. The incentives can range from the characteristics of the rules themselves – Are they simple and easy to apply? – to the existence of legal enforcement mechanisms, sanctions, and external inspection and oversight bodies.

Enforcement suffers from a host of weaknesses in Bulgaria. It is not clear that the necessary incentives and sanctions exist on the books, or that existing ones are used with any regularity. Interviews and media reports described improper behaviors that flout the rules with impunity. Courts and prosecutors continue to treat government decisions deferentially, while the more critical members of parliament (and government auditors) appear to exercise less than decisive influence here. Given the extent of political control over selection processes, and the paucity of independent expertise available to civil society, the fundamental question is *who will enforce?*

Table 7. Enforcement ratings

Question	*"Best practice" benchmark[44]*	*Bulgaria rating*
1. Are the rules on official appointments and terms of reference respected in practice?	Clear, public, and well-enforced appointment rules and terms of reference for each drug selection committee should be in place.	Poor
2. What sanctions are there for breach of the rules on conflict-of-interest? Bribery and other forms of corruption?	Well-defined sanctions should be applied if a committee member engages in inappropriate (unethical) conduct. By enforcing sanctions appropriately and effectively, this will also serve as a deterrent to any future misguided actions. In most countries, bribery legislation is included in the penal code or in special corruption legislation.	Average
3. Are there mechanisms in place to detect improper relationships – e.g. selection officials with undisclosed economic interests in the pharmaceutical sector? Are these effective in practice, or are such relationships accepted?	Any member on a drug selection committee should have no connections (formal or informal) to a pharmaceutical company. Committee members and external experts working with them should disclose all other involvement that may potentially create a conflict of interest. If overlapping responsibilities suggest conflict of interest, the committee member/expert should be compelled to either give up a particular role or resign. Public officials should have the duty, and the information necessary, identify if companies bidding for the same tender have any corporate relationships.	Poor

Education

This factor deals with the identification, socialization, and institutionalization of professional values and related standards of ethical conduct that decrease tolerance for corruption and promote integrity in public and private sector relationships. Education also concerns the capability, and the encouragement, of officials and outside stakeholders to exercise vigilance over the integrity of selection processes.

Education in Bulgaria has apparently seen less progress than other areas. There is no sign of government effort toward educating the public in this area. Codes of ethics exist for involved public servants and medical practitioners, and the industry has voluntary standards. However, no

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[44] *Source:* Cohen, Cercone and Macaya (2002), MSH & WHO (1997).

regular training appears to be offered. Nor are these standards accompanied by meaningful sanctions or enforcement efforts. Further, evidence from other countries suggests that relying too heavily on ethics standards – even in the medical profession, where they are long-established – creates risks of abuse and corruption. There is little to deter gift-giving, or to keep it from sliding into bribery. Bulgaria is missing potentially important opportunities to bolster the governance of its pharmaceutical systems through the reinforcement of ethical norms and public oversight.

Table 8. Education ratings

Question	"Best practice" benchmark[45]	Bulgaria rating
1. Do selection committees or officials inform, educate, or solicit input from stakeholders?	Drug selection committee members should regularly organize public education campaigns and consultations to ensure fair input on decision making and procedures.	Poor
2. How are these and other relevant officials trained in ethics and integrity rules? How stringent are these rules, in principle and in practice?	All drug selection officials should be trained regularly on ethical guidelines, standards of practice and consequences for any breaches.	Poor

Analysis of Integrity (TAPEE) in Drug Procurement by Hospitals

We now turn to the procurement of pharmaceuticals by hospitals, relying largely on survey results and to a lesser extent on qualitative findings. We present the TAPEE findings according to a numerical scale, based on indices constructed from relevant survey responses. We also provide the results of our efforts to show, quantitatively, a causal link from the TAPEE findings to the corruption indicators (discussed above).

Transparency

In Table 9 below, we compare the answers to the key questions meant to measure transparency of the procurement process[46] in each of the questionnaires administered to those directly involved with the procurement process. The "best answer" representing a high degree of transparency is shaded. Respondents were also asked about other influences on the committees' ranking of bidders. A few respondents said the hospital director's known preferences, or relationships between committee members and distributors. Many also said that a preference for brand name over generic medicines has an impact on procurement (43.2% of evaluation committee members and 35% of pharmacists).

Evaluation committee members report that bidders tend to be present together when bids are opened (59%), that each bidder is present only as his/her own offer is opened (14%), or that bidders tend not to be present at all (27%). When asked about committee member contact with bidders during the procurement evaluation process, few committee members said there was such contact. For the most part, the reason for the contact was to clarify the bid or request documentation – and most said this was done by phone or in person (rather than in writing, as required by law).

Evaluation committee members and hospital directors were asked: "How likely is it that someone would notice if an evaluation committee member has taken a bribe or informal payment?" At the

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[45] *Source:* Cohen, Cercone and Macaya (2002), MSH & WHO (1997).

[46] These are the same questions, though only from the evaluation committee questionnaire, used to create the TAPEE index discussed in the next section.

"high" transparency end of the scale, their answers were different; evaluation committee members said more frequently than directors that the circumstance would be very likely or definitely happen (16.3% versus 27% respectively).

Table 9. Transparency questions and answers (% of respondents in each respondent group)

Question and Answer Categories	Evaluation Committee	Pharmacist	Hospital Director
Do you get [director: give] any additional instructions or guidelines for the selection process beyond what is part of the bid documents?			
No	92.1	94.1	71.6
Yes	7.9	5.9	"Other" answers given, e.g., low price, economic benefit, etc.
How often is a contract signed with the bidder ranked first?			
never		2	
rarely & sometimes	1.4		2.2
often & always	98.6	98.0	97.7
Can the committee chairperson change the ranking prior to submitting it to the director?			
yes	3.5	2	
no	96.5	98	
Can the hospital director change the ranking?			
yes	4.8	4.2	
no	95.2	95.8	

These same two groups of respondents were asked about their hospital and potential means by which transparency takes place, e.g., publications about the hospital, media interviews given by staff, CSO or NGO share in hospital ownership, and having citizen(s) on the hospital board. Their answers were surprisingly different, and perhaps show a lack of knowledge on the part of evaluation committee members, who responded much more positively than directors (see the Annexes). A further measurement of transparency concerning the availability of information about the hospital is the availability of financial audit reports. (This question was only asked of hospital directors and so is not incorporated in the transparency index discussed below.) Three of four hospital directors reported that financial audits were made public (76.5%).

Accountability

Accountability was measured with the following questions. *Was the hospital fined for [making mistakes in procurement]*? One of four hospital directors said yes, whereas fewer than one in 10 (7.7%) of the evaluation committee members said yes. This could be a reflection of the committee members' relative lack of direct knowledge as compared to directors, or it could be that directors want to show their hospital in the best light. *In your opinion, how likely is it that a member of the evaluation committee is punished [as a result of being reported for taking] a bribe or an informal payment?* In a hospital with a high level of accountability, we would expect large numbers to say that it is very likely to happen or it definitely would happen. Six of 10 (61.5%) of hospital directors said it was very likely or would definitely happen, while 53% of evaluation committee members said the same, and fewer than half (47.4%) of pharmacists. *What is the most likely punishment for taking an informal payment from a drug distributor?* Answers covered a

range of possibilities from arrest to no punishment. Interestingly, directors report a higher likelihood of dismissal and of the person merely being dropped from next year's evaluation committee (see Table 10 below).

Table 10.   Likely punishment for taking an informal payment (% of respondents)

Possible punishments in decreasing order of punishment	Evaluation Committee	Pharmacist	Hospital Director
Arrest	2.8	0.0	2.4
Dismissal	24.8	27.3	40.0
Suspension	4.3	9.1	7.1
Demotion	2.8	3.6	7.1
Fined	7.5	7.3	5.9
Warning	18.5	32.7	7.1
Dropped from next year's committee	23.2	9.1	24.7
No punishment	5.1	5.5	1.2

Prevention

Several questions were asked about prevention, with some differences in subject matter across respondents based on their function. One question for evaluation committee members asked whether or not the same people serve year after year. Many said yes, they sometimes, often or always serve on the committee with the same people (66.8%). Greater variation in committee members can help to prevent opportunities for malfeasance in procurement. A further question pertains to contract versus bid prices. We expected that contract prices would be somewhat different than bid prices most of the time, but not by great amounts. What was interesting in respondents' answers was the high frequency of people saying that the prices were the same (evaluation committee 71.8%, pharmacists 60.9%). One could speculate that respondents thought this was the "correct" answer.

One of the key elements in any procurement process is to compare bid prices with current market prices. Evaluation committee members and pharmacists agree that someone does indeed make this comparison (85%, 86% respectively). They were also asked if they were provided with this information. While 69.1% of evaluation committee members said they were, almost all of the pharmacists said they were (96.1%). The difference again be due to the specialized nature of the pharmacist's position.

Another comparison of differences between evaluation committee responses and pharmacists concerns signed declarations of no conflict of interest (i.e. financial interest in a pharmaceutical supplier company). While most evaluation committee members confirm that they sign such a declaration (86.9%), only 54.8% of pharmacists say the same. (Perhaps pharmacists were thinking about their own jobs in the hospital and not as evaluation committee members.) Interestingly, only one of the six key informants who have served on evaluation committees mentioned the "declaration about no conflict of interest" when asked about procurement procedures, documentation, etc. Further, only 1% of the non-reticent evaluation committee members surveyed stated that someone had recused her/himself from the 2003 committee (the procedure to identify and remove reticent respondents is described below).

According to the PPA, committee members should not have a role in drafting the tender documents. We asked evaluation committee members and pharmacists about the number of hours they spend preparing tender documents. Over half the committee members (57%) report spending

at least some hours (between 8 and 30), preparing tender documents. Of the pharmacists who served on the 2003 evaluation committee, 85% also helped to prepare tender documents.[47]

Enforcement

We asked respondents if someone notices an evaluation committee member has taken a bribe or an informal payment, how likely is it that the person would report the incident. Answers across the respondent groups were about the same with approximately one in three people saying someone would very likely or definitely report it (evaluation committee members 36.7%, pharmacists 29.5% and directors 36.7%). Evaluation committee members and pharmacists were further asked how likely would such behavior be punished if it were reported. More than half of the respondents said it would very likely or definitely be punished (evaluation committee members 58.7% and pharmacists 57.3%).

Most survey respondents said that proper procedure is being followed in procuring pharmaceuticals in Bulgaria. For instance, no hospital directors admit to signing a contract with a bidder who failed to provide all necessary tender documents. This apparent adherence to procedure extends to the acceptance of bribes: no hospital directors or pharmacists say that an evaluation committee at their hospital has accepted a bribe from a pharmaceutical firm or supplier in the last year; only one evaluation committee member is willing to admit that someone on their committee had accepted a bribe. There are a few exceptions to this adherence to procurement procedure. We discussed previously hospital directors' stated compliance with bid-ranking rules. Also, evaluation committee members at 32 hospitals (of 126) admit to improper ranking methods.[48]

By law, the first ranked supplier should be offered the contract. We asked evaluation committee members how often the first ranked bidder signs the contract, and they reported (92%) that this occurs almost always. For those who said something less than "always," we asked why it doesn't always happen. They said that the first ranked bidder failed to sign the contract, with the exception of one committee member who said the hospital director offered the contract to a different bidder.

Education

We asked each of the key hospital staff involved in the procurement process if they had attended procurement or ethics training in 2003. Their answers reveal that very few staff received such training (see Table 11 below).

Table 11.   Hospital staff training (% respondents who reported receiving some training)

Type of training received in 2003	Hospital Directors	Pharmacists	Evaluation Committee Members
Procurement	12.4	16.9	8.8
Ethics	28.9	8.5	10.4

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[47] The issue of annexes, discussed previously from the directors' and suppliers' points of view, is an aspect of prevention. We also asked evaluation committee members and pharmacists about this – pharmacists are often involved in the contractual process, as they must then work directly with suppliers when ordering medicines. About 1 in 10 pharmacists (10.6%) said annexes are often added, which reflects the numbers given by hospital directors. Some evaluation committee members (6.4%) said this "often" occurs, and another 0.6% said it always happens – so, they too are aware of the frequency of contract annexes.

[48] Nearly 10% of the non-reticent evaluation committee members stated that they selected only the top bidder. Another 3% said they ranked the top two. Most committee members (44%) said they ranked the top three, and 42% said they ranked all bidders.

A number of the survey questions sought to measure the values of hospital staff. Here, we deal with answers given by evaluation committee members and pharmacists. The essential "values" question asked "How much do the following factors contribute to temptations to take informal payments from pharmaceutical companies?" The factors were: (1) Low salaries; (2) Belief that in capitalist systems making money is always good; and (3) Belief that taking the bribe does no harm. Possible answer categories were: it has no impact; it allows some people to justify taking bribes to themselves; or it allows most people to justify taking bribes to themselves. In a system where people have "high" values, we would expect to see a high percentage of people saying that such factors have no impact. In the responses, there is little difference between the groups, but some difference across the factors. More hospital staff say low salaries may justify accepting informal payments than a belief in the capitalist system. The answers to the "no harm" possibility suggest that many people believe that no harm results from such payments.

In addition, evaluation committee members and pharmacists were asked what they would do given these occurrences:

- An evaluation committee member strongly defending a particular medicine, where the member suspected corruption;
- The majority of the committee members advocating a brand name drug, despite the availability of a less expensive and equally effective generic;
- A supplier ranked first by the committee, but having a record of failing to supply medicines on time, and
- An evaluation committee member taking a gift or an informal payment from a supplier.

With regard to this last possibility, evaluation committee members were asked separately about gifts and informal payments, whereas pharmacists were asked about the two hypothetical situations together. Nearly one in 5 pharmacists would "do nothing," though many more (42.4%) would tell the hospital director. About the same percentage of evaluation committee members would tell the hospital director about informal payments, and nearly 1 in 5 would do nothing about gifts – and only 13.7% would do nothing about cash payments. They were more likely to report the matter to the committee chair (22.2% for gifts, 25.7% for cash). With regard to the situation where a committee member strongly defends a certain medicines, most respondents said they would tell the director or the committee chairperson. Fewer than 1 in 6 would do nothing. Regarding the other two hypothetical circumstances, all of the pharmacists reported that they would either (1) keep talking to convince fellow committee members (80%, 63.8% for the respective situations), (2) try to convince them for some time, but then give up (17.1%, 17.4%), or (3) complain to the hospital director (2.9%, 18.8%).[49]

Measuring overall integrity in drug procurement

Procurement is a complicated process and no one respondent in any given hospital is likely to have all the information about each step of the procurement process. The two best-informed respondents are probably the pharmacist and the director – but we had a serious problem with reticence here. We were able to identify around 35% of each set of respondents as being reticent (36% of directors and 35% of pharmacists were identified as reticent). We deleted them from the sample in order to get valid data. Since we had only one director and only one pharmacist at each hospital, we would have lost the hospital from the sample if we based the study on information collected from directors or pharmacists. For this reason we chose not to use data from directors or pharmacists in creating hospital-level measures of integrity.

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[49] While evaluation committee members answered these questions very close to the way in which pharmacists did, their frequencies were lower across the "more positive" answer categories, as some did not answer the questions.

Instead, we used information on procurement-related practices from evaluation committee members. Since there were multiple evaluation committee members in each hospital, we could drop reticent respondents without losing the hospital from the sample. Second, the presence of multiple evaluation committee members who were involved in, and asked about, the same processes allowed us to run consistency checks on the integrity data. For many of the questions, where the committee members were asked about the hospital's procurement process, the answers given by committee members were broadly consistent in the sense that there was agreement within many, but not all, hospitals.

The next step was the construction of indices of Transparency, Accountability, Prevention, Enforcement, and Education. These indices were created by combining information on several questions, and re-ordering the responses. Then, we tested how meaningful and well-measured these categories were. In addition to constructing TAPEE variables from the various questions in the evaluation committee data set, we also constructed another variable at the level of the hospital based on the reticence of the director and pharmacist. Hospitals were ascribed lower scores for a second "Values" variable if the director and pharmacists were identified as being reticent.

We found that *the TAPEE indices vary significantly across hospitals* in the sense that the responses of individuals covary systematically on specific questions. But these specific components do not vary in patterns that suggest that particular hospitals do well on all aspects of transparency (or all aspects of any of the other TAPEE variables). These data (based on non-reticent committee member responses) are graphically presented in Annex 10. Unlike our analysis of TAPEE in the selection process, the indices used for procurement were not based on international comparisons but rather on comparisons among responses from hospitals in Bulgaria. The highest mean response was given for the Education factor, and the lowest for Accountability (followed by Enforcement).

Linkage between Integrity (TAPEE) and Corruption

The importance of USAID/E&E's concept of integrity – TAPEE – rests on its expected causal nexus with corruption. All other things equal, we would anticipate an inverse relationship, i.e. higher integrity results in lower corruption. Is this relationship borne out in our research on Bulgaria?

In the context of the drug selection process, a statistical test of causation was not possible. The selection processes involve three groups of decision-makers, and overall a relatively small number people. This necessitated a qualitative approach. We designed the research so that findings would clearly either lend support to the expected causal relationship or weigh against it – but without purporting to offer final proof. We posited this causal chain:

1. Political-economic factors, or corruption "drivers," e.g.:

   - Drug firms' scramble to grab shares in a market dominated by government
   - Politicians, supported by industrial and patients' lobbies, seeking gain (political and personal) by influencing market share (selections)

→ Lead to:

2. Corruption, e.g. market allocation based on bribes, favors, illicit relationships – as evidenced by:
   - Experiences, perceptions, reports, and cases of corruption
   - Distortions in drug selection and reimbursement price-setting

→ If and only if there are:

3. Opportunities presented by weaknesses in government institutional integrity –

▪ As measured by TAPEE.

There are further complications. In the selection processes, it is a question of high-level or "grand" corruption. There would be serious legal, political, and personal consequences for anyone implicated (as contrasted with low-level bribery, which is often tolerated). Thus, reticence is a serious concern that we tried to mitigate in the interviews (mainly through the ordering and wording of questions).

Our objective was not to prove the existence of corrupt acts or their link with TAPEE – this is not the function of this kind of analysis. To take on such a task in this setting would require trained investigators and prosecutorial authority. Rather, our research and analysis of the selection processes has provided objective, qualitative evidence for the existence of political-economic drivers, corruption, and weaknesses in governmental integrity. The findings support the posited causal relationship, and provide a reasoned assessment and explanation of difficulties in the selection processes.

Regression Analysis of Corruption and TAPEE in Procurement

In the case of hospital drug procurements, we set up a rigorous test to measure the impact of integrity on corruption. To do this, we ran correlations and regressions between the TAPEE variables and corruption. We used the measure of corruption from doctors and nurses, to ensure a representative data set (see the above discussion of the data). Results of this analysis appear in Annex 11.

In broad terms, we did not find any significant results. Corruption is not correlated with any of the TAPEE variables, either in piecewise correlations or in a regression in which we include all the TAPEE variables. Nor does it appear that this problem is due to the way we have aggregated the integrity variables. The corruption variable is individually correlated with only 2/35 of the individual integrity questions[50] (as many as we would expect just by chance). The absence of results does not imply that the TAPEE variables are unimportant, as there are several possible reasons why we did not find a significant relationship between integrity and corruption. The data may be contaminated by persistent misreports, despite our efforts to weed out the reticent respondents. Or the doctors and nurses, from whose answers we created the corruption index, may be too uninformed about the procurement process. Another possibility is that the evaluation committee members in the most badly misgoverned hospitals may have been complicit in the corruption and provided misleadingly optimistic accounts. The least likely possibility is that we simply did not collect data on the right aspects of integrity – this was thoroughly checked (and largely ruled out) during the pre-test.

5. Conclusion

As we stated at the outset, this study aims both to test corruption assessment methods and to provide program-relevant input to USAID, globally and locally. In terms of methodology, we employed different approaches in analyzing the two levels in Bulgaria's pharmaceutical system – selection at the center and procurement at the hospitals. How do these two research components fit together? The two methodologies and data sets are complementary.

The qualitative approach taken in the first component enabled us to bring interview findings and secondary research together to make inferences about the relevant chain of causation. This runs

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[50] These questions concerned (1) whether the evaluation committee member attended any training in ethics and (2) the severity of punishment if caught taking bribes.

from political economy "drivers" to policy implementation outcomes, via opportunities (afforded by institutional vulnerabilities) and corrupt acts. What emerges is not a statistically validated picture but rather an indicative sketch of the dynamics of corruption in this system, based on a variety of qualitative evidence. Short of a prosecutorial investigation targeting individuals, the qualitative approach seems the best choice at the national level. Still, it needs to be carefully situated within a theoretical framework, and the findings interpreted with caution.

The results of the research on selection processes offer guidance on what to look out for at the level of procurement. In the latter, we used empirical survey techniques, informed by qualitative background work, to detect corrupt practices and their nexus with the posited integrity (TAPEE) factors. The quantitative approach enables statistical analysis of patterns across the country, at the "micro-institutional" level of the hospital. The surveys yielded a rich data set on corrupt practices and the various organizational and cognitive aspects of integrity. The overall approach allows us to paint one national "big picture" focusing on issues of grand corruption, and many "small" pictures creating a statistical landscape across hospitals. Also, notably, we devised a measure of respondent reticence. This offers a potentially critical boost to the credibility of corruption-related surveys.

The substantive results appear to fit together. Administrative or "petty" corruption often does not stand on its own. The pharmaceutical selection and procurement systems in Bulgaria offer a case where high-level deals seem to open the door to many lower-level opportunities for extracting rents (some, if not most, involving corruption). Our two-pronged approach provides a layered depiction of vulnerabilities and corrupt practice at two key points in the system.

The results on the link between integrity and corruption, however, are weak. The TAPEE regression for procurement turned up no significant results – whether due to a flaw in the TAPEE framework, or to the circumstances of this study. Probably both factors contributed. We stressed the "drivers" in the first study component, based on our view that integrity factors alone do not describe all the determinants of corruption. It is also possible that the TAPEE features that matter most are those in the central selection processes – i.e. that this is the real "choke point" where the main corruption occurs, and that hospital procurements simply divide the spoils. We can state this as probable but not certain.

So what?

Before we move on to our recommendations, we need to address directly a question that may linger for many readers. What is the importance of the methodology and of the findings – what do they reveal that was not already known?

The answer has several parts. First, the methodology goes well beyond the perception surveys normally used to calibrate the extent of corruption. It has enabled us to delve into both the design and the operation of the micro-institutions comprising a major sector of government activity. This approach yields a wealth of information on corruption vulnerabilities and corrupt practices. It also shows the wider linkages of administrative to grand corruption, and of corruption to pressures in the political economy that lead people to exploit (and intensify) institutional vulnerabilities.

Second, the findings show that corruption is a health issue, and that health is likewise a corruption issue. Any significant waste or distortion in the hundreds of millions of dollars of government expenditure on pharmaceuticals means a loss of anticipated health benefits. This is another sense in which corruption is like a disease – it subtracts value from each health dollar spent. Thus, effective health programming requires an anti-corruption dimension. Likewise, those concerned about corruption in Bulgaria need to translate that broad concern into action in particular sectors of public goods provision. Governance in the abstract will be of compelling interest to few; governance as the mechanism for producing public goods such as healthcare, justice, or efficient

markets will be of concern to many. In short, effective reform requires its proponents to show the concrete and tangible stakes of corruption – which we have tried to show in this paper.

Third, unlike most corruption assessment methodologies, the one employed here goes beyond measuring corruption perceptions and levels, enabling us to determine *where* it is located and *why*. This yields findings for policymakers and for USAID that are both empirically based and operationally relevant.

Last, this study and the companion studies suggest that institutional integrity (TAPEE) factors do not fully account for levels and patterns of corruption. Therefore, anti-corruption reforms and related aid programs will need to reflect a more encompassing view of the driving forces of corruption.

Recommendations for Bulgaria

The findings reported in this study suggest a number of possible reforms to strengthen integrity in both the drug selection process at the central government level and drug procurement by hospitals. Following are our key recommendations, roughly in order of priority.

1. A formula-driven selection model

The more Bulgaria can embed international standards in its system of drug selection, the better. As domestic expertise develops in both the technical and managerial aspects of pharmaceutical selection, it might make sense to take some of the rent-seeking pressure off the system. Perhaps the best way to get this done is through a radical simplification of the system. Bulgaria could adopt the WHO Essential Drugs List as the foundation for the PDL, a kind of baseline or "default." Ideally, such a baseline PDL would serve the purposes of both the existing Positive List and NHIF list – dropping one of these selection procedures should save time and money while reducing the number of decision-points subject to lobbying and illicit influence. If the WHO list is adopted as the baseline, then the PDL Commission could amend it, using special procedures. The Commission should be given a high procedural "hurdle" to overcome in adding to or deleting from the list (e.g., a change would need to be explained publicly – and perhaps also be revenue-neutral). In addition, prices could simply be set at an international benchmark – perhaps the average of the prices in the eight reference countries. The basic point here is to design a system that is driven to a great extent by mandatory formulas, like a currency board.

2. Stronger transparency requirements

A much more robust set of transparency requirements must be applied – *across the whole system of selection, listing, and procurement.* In our study, we found that the Access to Public Information Act worked to a large degree, in that government responded to all of our queries and made a good deal of useful information available. However, the APIA needs to be toughened – exemptions more narrowly defined, requirements of routine publication (without request) imposed, and procedures made simpler and more accessible. Beyond this, it may be worth considering the enactment of a government-wide "sunshine" law that requires all official decisions fitting stated criteria to be announced in advance, made on the public record, and/or taken in a public hearing. This would help address the present problem of certain decisions (e.g. MOH Expensive Drug selection) falling into a transparency void – undercutting the rest of the system by moving a portion, in effect, "off the books." Also, more comprehensive disclosure of information in websites, annual reports, and public forums is needed.

3. Tougher ethics standards and disclosures

Another important area of need is that of ethical standards – their definition, enforcement, and dissemination. Our analysis of selection processes showed significant laxity here. Also at the level of procurement, weak, or non-existent, reinforcement of ethical norms has multiple effects,

as shown by the surveys. These include relaxed views of gift-giving, the perception of bribery as a victimless infraction, and the failure of interested parties to recuse themselves. These problems can be addressed from several angles. One focus should be on civil servant, professional, and corporate codes of ethics. This is the "values" aspect of anti-corruption that is often ignored in contemporary technocratic approaches – yet the clarity of normative standards is a necessary part any successful strategy. There are codes in existence, of course, but all of the relevant groups should be held to a more robust standard of self-regulation, ideally backed by legal sanction and civic monitoring. On the procedural side, asset declarations and conflict-of-interest disclosures need to be applied more broadly (including to outside experts) and more stringently, and the vetting and verification of these documents taken much more seriously. Last, there is an obvious need for more, or more effective, ethics training.

4. Independent commissions for selection and procurement

Concerning drug selection, there are two related problems that need sustained attention – the difficulty of monitoring the highly technical analysis that goes into drug selections, and the lack of independence on the part of the selection commissions. Even though administrative appeals are available, these can only take into account legal and procedural regularity. Such review can check some forms of bad dealing, but will not capture hidden dealings that result in technically unsound decisions. Good substantive results require expertise and non-partisanship to be built into the selection process itself, and protected from intrusion by line officials of government. This is the essence of the independent regulatory agency (or commission) model used in many of the industrial countries. Experts on these commissions often have fixed terms, are confirmed by parliament, are either non-partisan or represent the full political spectrum, and are subject to rigorous review of their technical qualifications and potential conflicts of interest. They are separate from the executive chain of command. A variant of this approach might be to set up a non-governmental, non-profit entity to handle selection, or to designate an international or hybrid Bulgarian-international commission for this.

Hospital drug procurements may benefit from a similar reform. The World Bank, WHO, and some member countries (notably India) have developed the model of an autonomous medical supply purchasing corporation. In this model, governments (or in Bulgaria the hospitals) outsource drug purchasing to a company that handles tender and distribution processes, and is self-financing. The version of the model used in the Indian state of Tamil Nadu has introduced a high level of transparency through computerization, and is reported to be clean and efficient (see http://www.tnmsc.com).

5. Streamlined procedures

In the various approval, pricing, and selection processes by which medicinal drugs are introduced to the Bulgarian market, there are delays and inefficiencies that in some instances create opportunities for abuse. One model that could be employed here is the "one-stop-shop." The government, with the help of international agencies, could create a single process under a unified drug super-agency. A pharmaceutical company could simply make a single application for its drug (or a simplified combined application for multiple drugs), to be approved and (if the company so chose) listed. Such an approach would be consistent with the approaches taken in some other countries, and with the oft-cited need to combine some of the Bulgarian procedures (notably the PDL and NHIF lists). It would reduce the duplication and delay arising from the existence of separate (and to some extent inconsistent) market approval, price-setting, and listing processes. The use of one-stop-shops has had dramatic impact in business registration and foreign investment approval processes.

With regard to bidding and contracting in drug procurement, we face a classic abuse of discretion problem. The procurement process is complex, and the documentation requirements in particular

appear unjustifiably burdensome – and they require officials to cut corners in order to get business done. The decision about who benefits from bureaucratic shortcuts appears to be entirely discretionary and subject to abuse. The system needs a re-think in order to create even competition and open, accountable decision-making in this area. There are other aspects that would eventually need attention, such as a stronger deterrent to collusion among bidding firms, sometimes with procurement officials. However, streamlining the process would be a good initial step toward ensuring decisions based on merit rather than manipulation.

6. Stronger corporate governance and financial discipline in the hospitals

As is often the case in post-socialist transition, the transfer of ownership in Bulgaria's hospitals appears to have left unresolved some key corporate governance issues. In particular, the many hospitals with full or partial ownership by the municipalities have not operated within a hard budget constraint – rather, they have frequently gotten subsidies from the central government to cover operating deficits. The resulting "moral hazard" creates incentives for the municipalities to keep in operation hospitals that are inefficient (and in some cases corrupt), unaffordable, and superfluous from a healthcare planning perspective (i.e., excess hospital beds). At the same time, this arrangement has clear benefits in terms of local politics. Continuing reform in the healthcare sector will likely deal with this at some point, but in the meantime, the lack of financial discipline and strong oversight encourages undesirable outcomes such as overspending, mis-targeted spending, and corruption in medicine procurement.

This cluster of issues warrants attention from both the Government of Bulgaria and USAID. In particular, careful consideration should be given to steps that strengthen technically sound healthcare facility planning, as well as corporate governance and financial oversight of hospitals. A point of departure here might be to work with municipal councils that are beginning to monitor the hospitals. Along with a phase-out of subsidies covering hospital deficits, greater local transparency and cooperation on the part of the Regional Healthcare Centers and Health Insurance Funds would help in this regard.

7. Procurement accountability and oversight

In both parts of the study – but more clearly in the procurement surveys – responses showed a worrisome lack of accountability for breach of procedural and ethics standards. These findings are backed up by media reports on Bulgaria's handling of drug-related corruption scandals. Government has not sent a credible signal that these wrongs are taken seriously and will be punished. This much, at least, is clear from respondents' statements that the rules are frequently bent with little consequence.

At least two steps need to be considered here. First, government does need to send a signal of serious intent here – through some combination of policy pronouncements and a "get tough" campaign to enforce ethics and procurement laws. This, of course, will involve a political calculation to make this area a high priority, and to pay the price of upsetting the beneficiaries of the current system. Second, an independent commission overseeing hospital procurements, with power to approve or stop procurements, may strengthen discipline here (unless Bulgaria adopts an autonomous medical supply company model, which would make this step unnecessary). These procurements are already audited, but audit reports appear to have little impact – the findings require action by enforcement agencies that are politically accountable in a different way. The audit function could perhaps be combined in such a commission with a broader accountability mission, and given a higher profile and enhanced power to sanction.

Also, as a first line of defense against abuses, internal controls should be strengthened. This might include, for example, the placement of independent procurement experts on hospital evaluation committees (perhaps nominated by the NHIF and its regional branches), a stronger policy on

separation of tender design and bid evaluation personnel, and incentives for "whistle-blowing" by hospital officials involved in bidding processes. The latter could be a combination of protections for those reporting improper behavior and sanctions against those who come to know of such activities but fail to report it.

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ANNEXES

Annex 1. A synthesis of existing measures of integrity and corruption for Bulgaria

	Concept	Source	Definition	Bulgaria "score"	Points of Comparison	Additional comments and notes
1	Governance ratings	Freedom House (2004)	An overall rating of governmental quality, capturing stability, legislative and executive transparency; the ability of legislative bodies to fulfill their responsibilities, decentralization of power, and the freedom of the civil service from excessive political interference and corruption.	3.75 on a 1-to-7 scale, with 1 being highest	Slovakia = 2.25 Hungary = 2.50 Romania = 3.75 Croatia = 3.75 Russia = 5.25 Eastern Europe = 3.29 FSU = 5.13	Bulgaria falls in the middle between Eastern Europe and the FSU.
2	Constitutional, Legislative, and Judicial Framework ratings	Freedom House (2004)	Measures constitutional framework for protecting rights (including business and property rights), equality before the law, treatment of suspects and prisoners, judicial independence, and compliance with judicial decisions.	3.25 on a 1-to-7 scale, with 1 being highest	Slovakia = 2.00 Hungary = 1.75 Romania = 4.25 Croatia = 4.50 Russia = 4.75 Eastern Europe = 3.21 FSU = 4.82	Bulgaria is an average performer for a country in Eastern Europe.
3	Index of Economic Freedom	Miles et al. (2004)	An aggregation of 50 variables capturing trade policy, fiscal burden of government, government intervention in the economy, monetary policy, capital flows and foreign investment, banking and finance, wages and prices, property rights, regulation, and informal market activity.	3.08 on a 1 to 5 scale, with 1 best	Slovakia = 2.44 Hungary = 2.6 Romania = 3.66 Croatia = 3.11 Russia = 3.46 Eastern Europe = 2.93 FSU = 3.30	Bulgaria falls between Eastern Europe and the FSU on this measure. (Higher scores show a greater level of government interference in the economy.) 2002-2003. Economic freedom = "the absence of government coercion or constraint on the production, distribution, or consumption of goods and services beyond the extent necessary for citizens to protect and maintain liberty itself."

	Concept	Source	Definition	Bulgaria "score"	Points of Comparison	Additional comments and notes
4	Degree of state intervention	Hellman et al (2000)	Percent of firms responding "frequently" or more to the question on how often the state directly intervenes in investment, employment, sales, prices, mergers, dividends and wages.	10.2% of firms	Slovakia = 30.4 Hungary = 27.3 Romania = 13.2 Croatia = 7.1 Russia = 11.5 Eastern Europe = 15.64 FSU = 14.56	Bulgarian government appears less interventionist than in other transition countries. Based on the 1999 Business Environment and Enterprise Performance Survey (BEEPS). Averages taken across the seven dimensions of intervention.
5	Capture economy index	Hellman, Jones and Kaufman (2000)	The percentage of firms declaring a significant or very significant impact of corruption in influencing laws and policies (parliamentary legislation, presidential decrees, central bank, criminal courts, commercial courts, and party finance).	28% of firms	Slovakia = 24 Hungary = 7 Romania = 21 Croatia = 27 Russia = 32 Eastern Europe = 17 FSU = 21.46	Transition countries fall into two groups: low capture (most and least advanced reformers) and high capture (partial reformers). Bulgaria falls into the high capture group. Based on the 1999 Business Environment and Enterprise Performance Survey (BEEPS). Averages taken across firms, not weighted.
6	Accounta-bility of state officials	World Bank (2002), own calcula-tions	Percentage of "never" and "seldom" responses to the question: "If a government agent acts against the rules I can usually go to another official or to his superior and get the correct treatment without recourse to unofficial payments/gifts."	45.7% of firms	Slovakia = 49.1 Hungary = 45.2 Romania = 45.5 Croatia = 42.2 Russia = 47.3 Eastern Europe = 42.5 FSU = 44.5	Bulgaria performs poorly on this measure in relation to other transition countries. (Higher values indicate worse economic environments created by state officials.)

	Concept	Source	Definition	Bulgaria "score"	Points of Comparison	Additional comments and notes
7	Control of corruption	Kaufmann, Kraay, and Mastruzzi (2003)	Success in controlling corruption. Scores are estimated for 199 countries. The distribution of scores approximates a standard normal distribution. Higher scores indicate less corruption.	-0.17 (on a 0 mean, 1 standard deviation scale)	Slovakia = 0.28 Hungary = 0.60 Romania = -0.34 Croatia = 0.23 Russia = -0.9 Eastern Europe = -0.06 FSU = -0.67	Bulgaria falls between Eastern Europe and the FSU. Constructed by aggregating ratings from various sources (polls of experts and surveys of businesspeople).
8	Corruption perceptions index	Transparency International (2003a)	The level of corruption in the public sector as perceived by business people, academics and risk analysts (poll of polls). Higher scores indicate less corruption.	3.9 out of 10	Slovakia = 3.7 Hungary = 4.8 Romania = 2.8 Croatia = 3.7 Russia = 2.7 Eastern Europe = 3.6 FSU = 2.9	Bulgaria is perceived to be less corrupt than average for a transition economy.
9	Burden of corruption	World Bank (2002), own calculations	Percentage of firms stating that corruption is a moderate or major obstacle to operation and growth.	53.7 of firms	Slovakia = 50.0 Hungary = 23.5 Romania = 56.1 Croatia = 44.5 Russia = 29.1 Eastern Europe = 44.53 FSU = 38.26	Corruption appears to be a significant burden for businesses in Bulgaria, more so than for most transition economies. (Higher values indicate worse economic environments.)
10	Business costs of corruption	World Economic Forum (2002)	Position in ranking of 75 countries (1= country with smallest costs of corruption)	46th of 75 countries	Slovakia = 29 Hungary = 23 Romania = 62 Croatia = Russia = 63 Eastern Europe = 36 FSU = 48	Corruption results in greater than average costs to businesses in Bulgaria average for an Eastern European country and more in line with the FSU. Based on opinions of business executives questioned directly about the burden of regulations

	Concept	Source	Definition	Bulgaria "score"	Points of Comparison	Additional comments and notes
11	Place of corruption in relative ranking of problems facing businesses	Gray et al (2004)	Average over firms of their ranking of corruption among 22 obstacles of conducting business	7th highest of 22	Slovakia = 6 Hungary = 11 Romania = 5 Croatia = 6 Russia = 11 Eastern Europe = 7 FSU = 8	Bulgaria's score on this measure reflects the average situation for Eastern Europe. (Lower values denote a higher importance of corruption.) From the BEEPS2 sample data (2002)
12	Size of shadow economy	Schneider and Klinglmair (2004)	The ratio of informal economy to total GDP, in percentage points.	36.9%	Slovakia = 18.9 Hungary = 25.1 Romania = 34.4 Croatia = 33.4 Russia = 46.1 Eastern Europe = 29.0 FSU = 46.1	Estimates of the size of the shadow economy are produced using indirect econometric methods. The estimates are for 1999/2000.
13	Proportion of businesses in the informal sector	World Economic Forum (2002)	Position in ranking of 75 countries (1= country with smallest informal sector)	56th of 75 countries	Slovakia = 37 Hungary = 38 Romania = 71 Croatia = Russia = 53 Eastern Europe = 42 FSU = 37	Bulgaria has larger than average informal sector according to this measure. Based on opinions of business executives questioned directly about the burden of regulations
14	Size of administrative corruption	Hellman, Jones and Kaufman (2000)	Average estimated proportion of revenues typically paid by firms to state officials in order to "get things done" (e.g., licenses, tax collection, connection to public services)	2.1% of revenues	Slovakia = 2.5 Hungary = 1.7 Romania = 3.2 Croatia = 1.1 Russia = 2.8 Eastern Europe = 2.2 FSU = 3.7	Bulgaria score is average for an Eastern European country. Administrative corruption is "the extent to which firms make illicit and non-transparent private payments to public officials in order to alter the prescribed implementation of administrative regulations placed by the state on the firm's activities."

	Concept	Source	Definition	Bulgaria "score"	Points of Comparison	Additional comments and notes
15	Importance of bribes in the awarding of government contracts	World Bank (2002), own calculations	Average response to "When firms in your industry do business with the government, how much of the contract value would be typically paid in additional or unofficial payments/gifts to secure the contract?"	3.72% of a contract value	Slovakia = 3.75 Hungary = 3.56 Romania = 3.63 Croatia = 2.92 Russia = 3.20 Eastern Europe = 3.60 FSU = 3.34	Informal payments to secure contracts appear slightly higher in Bulgaria than in other transition countries. (Higher values indicate worse economic environments.) .
16	Relative importance of bribes for government contracts	Hellman et al (2000)	Bribes paid to gain government contracts as a percent of total bribes paid by a firm.	6.6% of bribes	Slovakia = 18.3 Hungary = 11.1 Romania = 7.8 Croatia = 44.7 Russia = 11.3 Eastern Europe = 23.19 FSU = 10.53	Bribes for government contracts are relatively less important in Bulgaria. Based on the 1999 Business Environment and Enterprise Performance Survey (BEEPS). Averages taken across firms, not weighted.
17	Frequency of informal payments for health care	Lewis (2000)		21%	Slovakia = 60 Hungary = Romania = Croatia = Russia = 74 Eastern Europe = FSU =	Bulgaria values taken from Balabanova (1999). Earlier work by Delcheva, Balabanova, and McKee (1997) revealed that 43% of respondents (using state health care in the past two years) surveyed in 1994 had paid for officially-free services.
18	Average informal health payments	Lewis (2000)	Average informal health expenditures (per capita) for health care and drugs as percentage of monthly income	4.39%	Slovakia = Hungary = Romania =4.11 Croatia = Russia = 3.78 Eastern Europe = FSU =	Bulgaria values taken from Balabanova (1999). Values are adjusted for Purchasing Power Parity (PPP).

Notes to Table 1:

1. Table adapted from Omar Azfar and Peter Murrell, "Romania: Business Registration, Authorization, and Inspection in Romania," Draft report to USAID E&E, November 2004.
2. Eastern Europe = Average of all former communist (or socialist) countries in Central and Eastern Europe, for which data was available. If estimates are available for fewer than five countries, no Eastern European average is given.
3. FSU = Average of all the countries that were formerly part of the Soviet Union. If estimates are available for fewer than five countries, no FSU average is given.

Annex 2. Research Methodologies Used

Qualitative Research

Key Informant Interviews

Key informant interviews were undertaken, as mentioned above, by IHHII experts. Informants included hospital directors and evaluation committee members, especially pharmacists, who often have a role in the medicine list or formulary, as well as proposal evaluation. We expected to draft survey instruments given the essential role these people play in the procurement process, but we could not bring members of these groups together in a group setting to talk about procurement issues and, especially, problems in procurement. Some of the issues were too sensitive to discuss in a group setting.

Focus Groups

Unlike the key informants, doctors, nurses, pharmacists, and patients, could be brought together to talk about their experience with medicine procurement or availability of medicines in hospitals. Focus groups are generally designed to learn how people think and talk about the issues, and what vocabulary they use, so as to allow for better-designed survey instruments and more precisely worded questions. Better-designed survey questionnaires result in better data.

Six focus groups were conducted at the same time as the key informant interviews were being done. Two groups consisted of doctors (16 total), one group of nurses (10), one group of pharmacists (5), and two groups of patients (17). With the exception of the pharmacists, none of the other participants had any direct knowledge of the evaluation committee and its work, though many people offered conjecture, rumor and hearsay. The general conclusion drawn by the groups' moderator was that the lack of both information and transparency around the evaluation committee led to doubts about the "impartiality" of the evaluation committees and "honesty" of the procurement process.[51] This conclusion allowed us to confidently determine that a patient survey would not be useful in studying a hospital's procurement of medicines.

Another conclusion we were readily able to come to involved medicine quality and availability - not one participant raised these issues as problems in their facilities or facilities with which they were familiar.[52] As a result, we did not include questions about quality of medicines (with the exception of questions about generics versus brand names) in the surveys, nor did we spend much effort on questions about availability, except to ask about immediate availability of a medicine in the hospital pharmacy.

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[51] "Impartiality" and "honesty" are taken from the Focus Group report conclusions, as prepared by FACT Marketing and Social Research, a survey firm with which IHHII has worked and hired for the purpose of conducting the groups and the surveys.

[52] Participants did point out when asked that there are "expensive medicines" that are not available and that, if wanted by the patient, must be procured by the patient at a pharmacy (other than the hospital pharmacy). Some participants thought the lack of expensive medicines might be evidence of the hospital's desire to gain financial profit. In fact, patients apparently often go to outside pharmacies for medicines, but this may not be at all unusual. Still, one problem all agreed upon is that patients lack education about their healthcare rights. Further, the Bulgarian health care system is in a period of "dynamic transformation and the rules undergo frequent changes," so that even physicians are sometimes ignorant of the rules. Lack of transparency was repeatedly raised as a problem, which is not uncommon for a system in flux.

Experts, Research, Analysis

The qualitative analysis brings in background literature, comparative data, and ratings based on outcomes of the Bulgarian selection processes (including comparisons against WHO-sponsored 'rational drug use' standards and international price guidelines). Our analysis of this material enables us to assess the pressures placed on the selection system – influences that may drive corrupt practices – and the outcomes of the system, in terms of the technical quality and cost-effectiveness of choices. We also review professional ethics norms, public official ethics rules, and government-wide integrity and anti-corruption systems – and assess their bearing on the selection processes.

We subcontracted a Bulgarian think tank specializing in health, International Healthcare and Health Insurance Institute (IHHII), to provide local expertise in procurement, hospitals, and health policy. We also hired Professor Jillian Cohen, an expert in pharmaceutical policy.

We contracted Judith Fisher, a pharmacy graduate student at the University of Toronto, to compare the Bulgarian drug lists to international standards. This analysis first compared the three Bulgarian lists and the WHO Essential Medicines List 13th Model (2003) by Anatomical and Therapeutic Category (ATC) code, and then compared each drug on each list by category. This strategy allowed a direct comparison of individual agents by therapeutic use. The comparison determined which agents appeared on the Bulgarian lists but not the WHO list, and vice-versa.

Survey Methods and Data

IRIS designed the survey instruments [describe] asked interviewers from Fact Marketing, and research firm affiliated with IHHII, to implement the surveys.

All respondents were asked questions to determine their potential reticence. Respondents received two envelopes, each containing a sheet of paper with two questions on it, where one question was underlined. One question was about some sort of negative or "corrupt" behavior, like *have you ever taken/offered a bribe?* The second question was a simple mathematical question like *Does 2+2=4.* Instructions asked respondents to answer the underlined question without indicating what question they were answering. In envelope 1, most respondents found the corruption question underlined. In envelope 2, only the mathematical question was underlined. In all of the descriptions below, we have indicated the number of respondents who said "no" to the question in envelope 2, thus indicating a reticence to potentially be seen as having participated in a corrupt behavior. In all of the data analysis, except with regard to suppliers (only 6 answered some of the survey questions), we have eliminated the reticent respondents.

Table 12.   Numbers of Respondents (out of 148 hospitals studied)

	Hospital Directors	Evaluation Committee Members	Pharmacists	Doctors	Nurses	Suppliers
Total # of respondents	139	440	111	551	707	6
Non-reticent (#)	90	317	73	398	455	NA[53]
Reticent (% of total)	35.3%	28.0%	34.2%	27.8%	35.6%	NA

Another check we ran on the data consisted of checking whether any two observations gave identical answers to suspiciously many questions. This may indicate data entry errors or collusion. We found little evidence of such problems, and deleted the few problematic observations.

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[53] None of the suppliers answered the envelope questions, so we have no reticent/non-reticent division. We can, however, surmise that all of the suppliers are reticent, given their refusal to answer many questions, and the small number of suppliers who were willing to answer even some of the questions.

Hospital Directors

Fact Marketing approached the hospital director (or deputy director in the director's absence) in every hospital, for permission to conduct the study, as well as for a face-to-face interview, and to request the director have a self-administered questionnaire completed by his/her staff. Out of the 148 cooperating hospitals, 139 face-to-face interviews were completed (126 of the self-administered questionnaires were returned to Fact Marketing). Forty nine directors/deputy directors were found to be reticent, leaving the answers from 90 to present below. The self-administered questionnaire was completely by a combination of hospital staff, e.g., the pharmacist and the accountant. All of these questionnaires are included in the data presentation.

Almost two thirds (65.5%) are men (34.4% are women). More than half (52.2%) of the directors are between the ages of 46 and 60. A little more than a third (36.7%) are between the ages of 31 and 45. Nine out of 10 have a master's degree. About 85% said they were somewhat to completely comfortable, which is corroborated by the interviewers' rankings. Interviewers equally ranked the respondents as honest.

Pharmacists

The chief pharmacist was approached by an interviewer for a face-to-face interview in each of the hospitals. Out of the 111 pharmacists who agreed to be interviewed, 38 were dropped as reticent. As a result, the data presented below covers the remaining 73 pharmacists.

Three-fourths of pharmacists in our sample are women. Nearly two-thirds (66.2%) have a Master's in Pharmacy or Medicine. Most (61.1%) are between the ages of 46 and 60, with another 22.2% between 31 and 45. Most (62%) report having been at their current positions less than 5 years. When asked about their previous position, nearly half (44.6%) were also at that position for less than 5 years.

Nearly 2 of 3 respondents (63.9%) said they were completely comfortable with the survey, and another 22.2% said they were somewhat comfortable. Upon assessing their colleagues' comfort level, however, respondents were more hesitant with one third (34.7%) saying colleagues would be completely comfortable, and 25% saying somewhat comfortable (29.2% said they didn't know).

Interviewers were also asked to report respondents' comfort level. Nearly half (47.2%) reported respondents as completely comfortable and 29.2% said they were somewhat comfortable. Interviewers reported their perception of the respondents' honesty about the same with 47.2% saying completely honest and 30.6% saying somewhat honest.

Evaluation Committee Members

Where possible, at least 4 members of each hospital's evaluation committee were interviewed in face-to-face interviews. Some hospitals had committees consisting of the required 3 people, making 4 interviews impossible. The attorney on each was approached, but often not reachable, as s/he is often not regularly employed by the hospital, but has his/her own practice elsewhere. Fact Marketing interviewed 440 evaluation committee members, where 317 were found to be non-reticent.

Just over half (51.7%) of the committee members are between the ages of 31 and 45, with another 39.4% between the ages of 46 and 60. About 3 of 4 have a master's degree. They report themselves as being somewhat or completely comfortable (82%) with answering the questions. While 62% said their colleagues would also be comfortable, more than 1 in 4 said they don't know how their colleagues would feel.

Doctors

The doctors' survey consisted of a self-administered questionnaire and the two envelope questions to measure respondent reticence. Interviewers received back 551 completed surveys from doctors, where 153 were dropped from this analysis as they said "no" to the second envelope question, which was *Does 2+2=4?* The results presented below, therefore, only include responses from the 398 doctors who are thought to be non-reticent.

Of those, 45% are men and 53% are women (2% missing). More than 3 out of 4 doctors (78.7%) report having a master's degree. Nearly a third of the doctors have been in their current position for fewer than 5 years, 17% for 6-10 years, another third for 11-10 years, 15% for more than 21 years, with 5% missing. The mean age is 44. Fewer than a quarter of the doctors (22.4%) have received ethics training. More than half participated in some seminars or conferences in 2003. Generally, doctors reported being comfortable with answering the survey questions (79.7% said average to completely comfortable).

Nurses

Like the doctors' survey, the nurses' survey was a self-administered questionnaire with the two envelope questions designed to measure reticence. Of the 707 nurses questionnaires returned to Fact Marketing, 252 (36%) were dropped for answering "no" to the mathematical question in envelope 2. The results discussed below reflect the answers given by the remaining "non-reticent" nurses.

Almost all of the nurses are women (96.7%, 0.7% said they were men, and the rest didn't answer the question). One of four nurses reported their comfort level as being "average," while nearly half (48%) said they were somewhat to completely comfortable answering the survey questions. More than one third said "don't know" to the same question asking their opinion about their colleagues' comfort level.

Suppliers

There were 24 suppliers of medicines named by the 148 hospitals that participated in the study. Fact Marketing identified 44 potential suppliers over all. Of those 44, only 6 partially completed the survey, which consisted of two parts (all 6 completed at least some of part 1, while 5 of the 6 completed some of part 2), despite the fact that most suppliers accepted and kept the initial appointment to meet with the Fact Marketing representative. The overwhelming reason given for refusing to take part in the study was confidentiality. Despite assurances from Fact Marketing, IHHII, and IRIS, suppliers said the surveys requested confidential information, which they would not share despite assurances about data security and confidentiality of suppliers' responses. Despite their reticence, when the six suppliers who answered some of the questions were asked about their comfort level in answering questions, 4 said they were completely comfortable, one said somewhat comfortable, and the sixth said "average."

Tests of TAPEE Indicators

The basic tests we ran hinged on whether the reordered answers to the questions in (say) the Transparency category were correlated with other questions in the Transparency category. In fact, we found that few were significantly positively correlated and many were negatively correlated. Nor could we ascribe the low or negative correlations to our assigning questions to the wrong categories, because the correlations for individual questions across integrity categories weren't high either. Another test examined whether there was significant variation across hospitals in terms of TAPEE variables, and for an aggregate TAPEE variable equal to the average of all the integrity questions. Here, the variation across hospitals was significant for most TAPEE aggregates. The Transparency level reported by one respondent was correlated with that reported by other respondents at the same hospital.

Annex 3. Integrity Factors (TAPEE)[54]

Transparency refers to the ability of citizens, public officials and civil society (principals) to obtain the material information that they need in order to make informed decisions and hold public sector agents accountable. Public sector agents include public institutions and officials whose mission is to make, implement, and enforce the official rules of the game, provide and allocate public goods, and collect and expend public funds. Principals include the stakeholders who are the customers, users, and intended beneficiaries of the institutions and organizations created for their benefit.

Substantive transparency is the spread of information (e.g., regulations, procedures, fee schedules, etc) from public sector agents to private sector principals most directly interested in the services provided by agents. Procedural transparency refers to open and inclusive, and participatory processes (e.g., freedom of information disciplines and sunshine laws) so that political and civil society principals can affect the official rules of the game, the provision and distribution of public goods, and the expenditure of public funds.

Accountability refers to rules specifying the relationships between public officials' behavior and performance, on the one hand, and rewards and punishments, on the other. It includes both punishments for corruption and violation of rules, and incentives based on the both quality of service delivery and adherence to rules and procedures. Accountability can be thought of in three layers, between voters and politicians, between politicians and bureaucrats, and between superior and subordinate public officials. Thus, elements of accountability are the following: systems of internal and external monitoring and controls within the state apparatus; and interactions involving societal institutions and organizations that increase external monitoring and thus reinforce the duty of public institutions and public officials to account to the public and stakeholders.

Prevention refers to the structuring of institutions and organizations so as to decrease opportunities for corruption. This includes reducing monopoly and discretion, rightsizing the civil service, and separating private and public actors and formalizing the relationships between them. It also includes identifying and eliminating perverse incentives by facilitating meritocracies founded on competition, merit, and living wages. Thus, restructuring for prevention employs interventions that eliminate unilateral decision making, promoting competition and choice, curbing the unfettered discretion of public officials, replacing arbitrary, subjective, ambiguous, complex, and otherwise opaque and informal rules of the game with objective standards and mandatory rules that trade off flexibility for simplicity, certainty, and uniformity of application.

Enforcement refers to whether incentives exist for compliance with the rules defined in accountability and prevention. This includes criminal sanctions for corruption, and administrative sanctions for negligence, poor performance, or non-compliance with the rules of the game. The presence and effectiveness of anti-corruption agencies, ombudsmen and auditors can be thought of as components of enforcement. It also includes simplification and clarification of legal and regulatory frameworks so that compliance is easier and more easily monitored.

Education includes awareness and values. It embodies the intrinsic motivations of public officials to avoid corruption even when a simple cost-benefit analysis would induce such action. It involves changing behaviors through communicating the causes and consequences of corruption. It involves knowing what corruption is, who in the public and private sectors benefits and who loses from corrupt

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[54] From Murrell, Peter, "Report on Business Registration, Authorization, and Inspection in Romania," Draft report to USAID E&E, September 2004.

practices. It is awareness, of both stakeholders, concerning the nature, causes, dynamics, costs, and adverse consequences of corruption and the benefits of specific reforms and the opportunities for change. It embodies the identification, socialization, and institutionalization of public sector values, professional values, and societal values and related standards of ethical conduct that decrease tolerance for corruption and promote integrity in public and private sector relationships.

Annex 4. Hospital Procurement Process in Bulgaria: Open Procedure

Hospital determines there will be a competition	Hospital drafts tender documents	Hospital publishes competition in State Gazette & a local or national newspaper

Hospital creates evaluation committee (at least 3 people, one must be a lawyer)

Hospital sends information to Register of public procurement

Evaluation committee opens bids and determines if they are complete.

Bid is incomplete.

Bid complete. Proposal continues to the next step in the evaluation process.

Bidder is dropped from competition.

Evaluation committee decides to inform bidder of problem and allow bidder to supply missing documentation.

Bidder agrees to supply documentation.

Bidder does not supply documentation.

Committee reviews bids, ranks them. Paperwork given to committee chairperson.

Committee chairperson gives paperwork to hospital director.

Bidder declines. Director offers contract to third-ranked bidder.

Bidder declines. Hospital director offers contract to second-ranked bidder.

Hospital director reviews paperwork, offers contract to first-ranked bidder.

Bidder accepts. Competition is over.

Annex 5. Pharmaceutical industry overview

The pharmaceutical industry is one where gaining a share of the huge markets (for example, $200 billion per year for prescription drugs in the U.S., Angell 2004) requires tremendous capital outlays for a combination of research and development on innovative drugs (although the amount invested in R&D is often exaggerated), marketing to patients and physicians, and influence activities aimed at policymakers and medical associations. Given the decline in the pace of innovation and the costs associated with drug development, the pharmaceutical industry has since the 1980s undergone a series of mergers and acquisitions which has led to the creation of mega-firms.industry.

The pharmaceutical industry can be described as one of oligopolistic competition – with a small number of large firms coexisting, and even cooperating, in the broad market, but with sometimes fierce competition in particular sub-markets (e.g. families of drugs, treatments for particular categories of conditions, generics). Other features of the market include price inelasticity and information constraints -- due to the privileged position of the physician as prescriber and the fact that the industry has better information about its drugs than the government -- and the irrelevance of price to many patients in those countries with third party payment systems or with functioning health care systems but certainly this is not the case in developing countries (McIntyre 1999). In the U.S., moreover, the growing predominance of volume bidding (e.g., by HMOs and pharmacy benefit managers) for prescription drugs, more akin to wholesale arrangements, as compared with retail sales, has raised new antitrust concerns about price coordination among drug firms and vertical integration or exclusive dealing arrangements in the supply chain (Levy 1999). This situation reinforces tendencies toward industry "capture" of regulators, as well as the intermingling of commercial and political interests.

Although much pharmaceutical research has been done by governments and universities, the production of drugs is largely in the hands of corporations. For companies, getting established or defending a position in the market is of all-consuming importance. Once a drug is established, patent protections and stable demand can make it hugely profitable for many years – with marginal costs of production being extremely low. Little wonder, then, that drug companies focus heavily on developing patentable variants of existing "blockbuster" drugs so as, in effect, to extend the life of their pharmaceuticals beyond patent expiry. This is the phenomenon of "me too" drugs (Angell 2004) The industry also relies heavily on intellectual property protection which gurantees twenty-year market monopolies pursuant to the Trade Related Aspects of Intellectual Property Rights (TRIPS) Agreement, which is governed by the World Trade Organization.

Hedging their bets, drug companies in the U.S. have also in recent years unleashed a wave of advertising aimed directly at patients – especially the elderly, known to be an especially demanding and politically mobilized cohort when it comes to health issues (Angell 2004). The message of these ads, often explicitly stated, is that patients should persuade their doctors – and by extension their health plans – to prescribe the new medicines being advertised.

Annex 6. Administrative appeal concerning the Positive List

The foreign drug producer associations brought an appeal against the Positive List Ordinance in Bulgaria's Supreme Administrative Court. They assert that the various approval and listing processes are applied in a way that costs them 10-15% of their expected annual revenue, or as much as 28 million euro. They cite several problems with the processes. First, they argue that the Positive List Commission is operating on the basis of "missing regulations" – i.e. that they have published no standards for decision and in fact apply only a rough and subjective cost-effectiveness measure. The Commission's decisions are not "motivated" or backed by administrative standards, and so shed no light and offer no guidelines to prospective applicants (i.e. importers) who have to assess risk/benefit. Only a very short time (one day, according to a drug firm) is permitted for public comment on the draft Positive List. Since the Ordinance gives the Minister of Health authority to approve or return Commission decisions, the producers argue that the Minister controls the process. They also argue that the Ordinance contravenes the Law on Human Medicines and Pharmacies, e.g. by including brand-names. Second, the Positive and Reimbursement Lists apply similar criteria and are therefore said to be duplicative, having no rationale other than to interpose a "filter" protecting incumbents from unwanted competition (Appeal to the Supreme Administrative Court 2003; producer interviews and position papers; www.capital.bg/weekly, various issues 2003-4).

The Court denied the Associations' appeal. The Court found that the Ordinance properly allowed the listing of brand-name drugs under each INN, in order of cost-effectiveness. The Court also held that a challenge to the substantive pharmacoeconomic analysis used by the Commission in determining this rank-order was beyond the Court's authority – it is a technical matter within the legal discretion of the Commission. Likewise, the use of price comparisons and other factors in drug selection are within the Commission's operative discretion. The Court noted that an appeal of the PDL Commission's decisions would lie elsewhere, and that it could deal only with the appeal against the PDL Ordinance itself – which it upheld as proper. (Republic of Bulgaria, Supreme Administrative Court, Decision no. 3968, April 30, 2004.) Opinion was predictably divided on this outcome, with officials seeing it as vindication and the appellants viewing it as an invitation to abuse. In the context of the Association's appeal, the court's decision, while disappointing, can be justified on the basis of narrow administrative law principles and a large scope of deference to official policy decisions. The possibility of personal or political bias in selection decisions is not as easily addressed by an appeals court, but requires some redesign of the selection processes themselves.

Annex 7. Ethical guidelines for pharmaceutical producers

Increasingly, the pharmaceutical companies are subject to voluntary industry codes, mainly aimed at marketing behavior – to some extent backed up by statutes on fair competition, bribery, and influence-peddling. For example, the Pharmaceutical Research and Manufacturers of America (PhRMA) in 2002 adopted a voluntary Code on Interactions with Healthcare Professionals. It provides a series of rules based on the underlying principle that such interactions must focus on producing benefits to the medical profession, health-related research, and patients. Thus, industry-sponsored events may include meals but not entertainment, and any items provided to practitioners should be of no more than U.S. $100 in value. Further, direct sponsorship of individuals at conferences and events (rather than of the event as a whole), and token consultancies to justify payments to individual professionals, are considered improper. While these seem to be sensible rules, they lack credibility to the extent that the industry has set up no enforcement or sanctioning mechanisms. Moreover, the rules offer a revealing glimpse at real practices that have raised the industry's concern about its image. The American Medical Association has similar rules aiming to prevent the involvement of the AMA in the production or advertising of pharmaceutical products.

These guidelines exist, not only in the United States but in many industrialized countries. While emphasizing patient-care, the general approach used by the Canadian Medical Association's policy on *Physicians and the Pharmaceutical Industry* is not inconsistent with that used by the AMA and the ACP. One of the general principles of the CMA policy requires the primary objective of interactions between physicians and industry to be the advancement of health of Canadians rather than the private good of either physicians or industry.

The Ethical Guidelines of Royal Australian College of Physicians takes a more general approach by stating that benefits or subsidies received from pharmaceutical companies must leave physician's independence of judgement unimpaired. As a general rule, arrangements between physicians and pharmaceutical companies should be open and transparent. Physicians must judge for themselves what is and is not acceptable, e.g. patient counselling or teaching aids. Non-service items should in general not be accepted. However, there is an obvious gradient of acceptability from items of trivial value to more substantive items, acceptance of which anyone would find objectionable. The appearance of impropriety should be considered before accepting lavish dinners and entertainment, even if accompanied by a scientific presentation (Cohen and Marshall 2004). But these are simply guidelines and not subject to rigorous enforcement.

In the U.S., the announcement of the PhRMA rules also coincided with increased scrutiny, by the Department of Justice and the Inspector General of the Department of Health and Human Services, of pharmaceutical marketing practices that appear to run afoul of federal anti-kickback laws. The pharmaceutical industry spends some U.S. $12 billion per year on marketing to healthcare providers. U.S. federal and state officials are concerned that some of this activity may amount to payoffs for doctors or hospitals to favor certain drugs for non-therapeutic reasons. Of special concern are patterns whereby providers choose drugs offering a higher "spread" between the cost to the provider of acquiring a drug and the (higher) price level at which the provision of the drug is reimbursed by insurers or the government ("Provider-Vendor Relations," *Health Care Fraud and Abuse*, vol. 5, no. 12, 1-4, January 14, 2003, ALM Properties, Inc., Lexis/Nexis).

Annex 8. Corruption by doctors: a question of values?

Physicians in many publicly-financed health systems are accused of corruption for such practices as accepting informal payments. Research on informal payments in Bulgaria suggests that some of this behavior falls within the definition of what is professionally acceptable – i.e. *ex post* payments intended as a sign of gratitude (but not up-front payments) (Balabanova and McKee 2002). The practice of giving gifts to physicians is not peculiar to Bulgaria; it occurs or has occurred in many societies. The difficulty here is that the distinction between a gift and a bribe appears difficult to maintain, especially where physicians function in state systems or institutions, and where they are underpaid and therefore motivated to increase their earnings. This is but one example of normative dissonance in the healthcare field. In this case, both the tradition of gratitude and the legacy of bribery from the late socialist and early transition periods conflict with the rules of the healthcare system, which require that care be provided free of charge or for legally-determined fees.

A different example, from the U.S., helps to illustrate the principle. Physicians are required by tradition and by professional standards to act in the best interest of the patient. At the same time, both private and state-financed insurance systems place limits on the kinds of care and the types of drugs that can be prescribed, in the interest of overall cost-effectiveness. (Further, the AMA Principles of Medical Ethics [www.ama-assn.org/ama/pub/category/2512.html] state that physicians should respect the law.) Physicians frequently bend the rules of these insurance systems in order to secure, affordably, the best treatment for their patients. This involves the physicians in a range of practices, from innocently cutting corners to outright fraud. Further, the increasing prevalence of insurance and Medicaid/Medicare fraud in the U.S. (Hyman 2001) cannot be explained by this kind of behavior alone. As more doctors cross the line into fraudulent practice, schemes of fraud and corruption that serve the narrow self-interest of physicians and others seem to become more frequent. The conflict of norms may not have created corrupt behavior, but it has likely made it easier.

What evidence is there that ethics codes governing the medical profession have an impact on physicians' behavior? We have previously cited studies of interactions between physicians and drug companies in the U.S., showing that the prevailing ethical norms in the profession have not prevented the accommodation, however uncomfortable, of commercial conflicts of interest in the selection and use of pharmaceuticals by doctors and healthcare systems. A study of healthcare in Latin America (Di Tella and Savedoff 2001) suggested that informal payments and other forms of corruption, many involving physicians, are common in the region's hospitals. A study in Russia (Moscow Public Science Foundation 2003) reached a similar conclusion for that country.

In Central and Eastern Europe, this pattern also appears. In fact, an in-depth survey of four countries in that region (Miller et al. 2000), including Bulgaria, reached an even more striking conclusion: physicians working in hospitals admit to *engaging in corrupt behavior with greater frequency as compared to most other officials* (and on a par with traffic police and customs officials). In many societies, this would be considered shocking, given the prestige and the longstanding ethical traditions of the medical profession. The analysis in the study suggests that this pattern of behavior arises from the combination of opportunity and bargaining power (as in the phrase "If you pay, we'll operate immediately"), with various forms of moral self-justification (low pay, social acceptability of gifts, and the prevalent expectation that higher governmental officials would tolerate the behavior). In other words, traditions of professional ethics seem to vary in strength across societies – so that in many cases they can recede in the face of countervailing pressures created by opportunities and expectations.

Annex 9. Detailed Integrity (TAPEE) Analysis: Drug Selection

Transparency

1) **Are selection guidelines and inclusion/exclusion criteria published and available? Are they clear?**

Bulgaria's rules in this area are evolving. The PDL decree was adopted in April, 2003, and the first list created in December of that year. The NHIF used an ad hoc list at least until the end of 2003, when it was made to conform to the PDL, and the regulation governing the NHIF's selection process only came into effect in August of 2004.[55] The MOH list was created in 2000, and the governing regulation was amended in October of 2004 with a view to the eventual updating of the list. Thus, the following discussion deals with both the functioning of the system under the prior rules and the quality of the newer rules.

The regulations now governing the three lists (PDL, NHIF, and MOH) state broad guidelines for inclusion, mainly related to the kinds of diseases and conditions that the drug lists are intended to address. For example, the PDL decree lists seven categories of disease – presumably those given high priority due to their impact on public health – that medicines on the PDL should be used to treat or prevent. The regulation for the MOH list does much the same. The NHIF Regulation of August 2004 states that drugs for the NHIF list are to be selected from the PDL, and further, that they are for outpatient use and that any compounds selected must also be on the reimbursement lists of three out of a list of eight countries in the region. (Some additional guidelines are given, for example, in the National Framework Contract.)

Participants in these processes, and knowledgeable observers both within and outside Bulgaria, describe these criteria as inadequate. The criteria do not meet the international best practice standard, stated as follows: "The rationale for drug selection should be clearly presented and backed up with the appropriate scientific and economic justifications" (Cohen et al 2002: 71). Bulgarian officials in this area disagreed as to whether the PDL criteria provided sufficient transparency, while outside observers, including a member of parliament, were united in the view that the criteria did little to clarify the basis of selections, nor to address the problem of subjective and technically weak decisions. Drug company representatives complained of vagueness, citing the industry's lawsuit challenging the PDL and suggesting that official discretion was such that a PDL applicant's initial rejection could be overturned with the submission of additional information.

The other two lists (NHIF and MOH) did not prove any better. Public officials and firms agreed that the guidelines these institutions used in their drug selection processes were weak or, in effect, non-existent. As evidence, one official cited NHIF drug reimbursement budget overruns of 67% in 2003 – a result of Bulgaria's inexperience in this area, embodied in weak criteria and resulting selections. There were also many complaints about NHIF's use of internal, unpublished rules. These latter observations apply to the prior rules that were in effect through 2004. Further, despite the subsequent publication of rules, it is difficult to conclude that real, operational selection criteria – as opposed to general guidelines or principles of inclusion – have been disclosed. Indeed, the NHIF initially refused IHHII researchers' request, under the APIA, for a copy of the draft NHIF Reimbursement List regulation. On the other hand, the researchers were able to obtain minutes ("protocols") of the Transparency Commission meetings at which the draft regulation and other matters were discussed.

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[55] NHIF has often been criticized for secretiveness, but it did publish a few press releases in 2004, and held a meeting of the various pharmaceutical producer associations, in May, to discuss its draft regulation.

A further concern, expressed mainly by the foreign drug companies operating in Bulgaria is that the selection process *as a whole,* starting from application for market authorization and ending with local procurements, creates a series of hurdles that subject companies – especially foreign producers – to discretion and delay. This allegedly enables officials to protect domestic (and favored) producers through selective enforcement. In any event, it appears that Bulgaria's approval and listing processes do not comply with the criteria for establishing drug lists set forth in the EU Transparency Directive (89/105/EEC). International best practice standards[56] suggest that the government should have clear guidelines specifying what criteria are applied to drugs on any public formulary. A transparent methodology that determines the drugs' necessity for the health needs of the population and cost-effectiveness should be uniformly applied.

Rating: *poor*

2) **Is the following information about committees and officials making selection decisions published and available: their names, basis of appointment, responsibilities?**

The Positive List Commission members are appointed by the Council of Ministers. The method of appointment and the broad terms of reference for the Committee members are stated in the PDL decree. The decree states generally that experts can be brought in to assist, but do not have a voice in the decisions.

Some officials mentioned that members' names are published in the state gazette. IHHII researchers were not able to find this list in the gazette but did obtain (through an APIA request) copies of the COM decisions appointing and replacing members of the Committee. This, however, provides only a partial accounting of those participating in PDL decisions, since a large number of external experts conducted analyses and made recommendations in the process. Under the CPDL Working Rules, the Commission does not publicly disclose the identities of these experts. Rather, applicants seeking this information must request it from the Commission Chair. IHHII researchers obtained the names of these experts through the APIA process. No documents detailing appointment procedures for these experts, nor their terms of reference, were made available to the researchers. Outside parties (including firms and journalists) also reported that they had been able to learn the names of Committee members (and in some cases the experts), usually through informal queries.

For the Reimbursement List, the NHIF designates committees to carry out different parts of its process, from initial selection to the evaluation of offers and contracting. Regarding evaluation and contracting, regulation provides that half the members of this commission are to be drawn from NHIF, and the other half from the medical and dental associations. The NHIF Director appoints the chair. This group reviews submissions, makes selections, and negotiates terms with the drug companies. Officials stated that appointments to the NHIF committees are made by Public Order. Outsiders said this information was not published, but could be requested (again, informal queries appeared to be the preferred method). The regulation on the NHIF list gives only a general statement of the appointment methods and terms of reference.

No information is published on the selection process for the MOH list. Thus, the process is essentially internal to the Ministry, with any information about, or contact with, decision-makers being informal. The Ministry appoints a working group to assess recommendations by outside experts and constituencies, and make selections.

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[56] In this paper, we draw our "best practices" standards from Cohen et al (2002) and MSH & WHO (1997). Note that these standards are uniform, and do not differentiate between industrial and transition countries.

Expert views on international best practice (see Cohen et al 2002) hold that selection committees should be selected on the basis of professional expertise. This ensures sound substantive decisions and helps minimize the influence of political and other non-merit bases for pharmaceutical selection. This, of course, can only be evaluated by the public and be subject to external accountability if the names, appointment methods, and terms of reference of committee members are publicly known. The method of appointment should also be clearly stated and publicly available. Ideally, all of this information should be available in government formulary manuals and websites. The Bulgarian system lives up to this standard in only a very partial sense – there is some transparency in the PDL process but very little in the NHIF and none in the MOF processes. Even in the PDL case, government has to be asked, even pressed, to provide names.

Rating: *poor*

3) How do stakeholders learn about decisions?

Decisions on all three lists are announced to the applicant firms, and to the public at large. For the PDL, the decree provides that applications are accepted up until a cut-off date (31 May). After that, the Committee has four months to decide and notify the applicants. This response deadline reinforces both transparency and accountability. The decree, not unreasonably, allows this period to be extended (tolled) while applicants respond to Committee requests for additional information. The decree provides for this tolling provision to be spelled out in regulations. However, this is not the case. Drug companies have complained of seemingly unlimited delays in the announcement of decisions, which are made public at a press conference.

The other two lists are also published, but no time limit is imposed for decision-making. The NHIF invites applications (bids) from firms holding market authorizations for the relevant INNs, giving them 15 days for submission. The NHIF then makes its selections, based on applicants' conformity with contracting requirements and price criteria – the evaluation of offer prices is done in the presence of applicants. Once decisions are made, applicants have three days to appeal any negative decisions affecting them. Companies complain that this appeal period (their only opportunity for formal comment on selection decisions) is too short. Final decisions are posted on the internet. The process used for the MOH list is not specified in detail. Applicants are informed of decisions by letter. The list is then officially published.

Best practice indicates that drug selection decisions should be publicly available on a timely basis. In addition, a formalized and regular appeal process for applicants who have their drug submissions rejected should be in place. This will ensure standards of drug selection are transparent, clear and fair.

Rating: *average*

4) Are the drug selection meetings open to the public? Announced in advance? In fact attended and covered by the media?

The PDL and NHIF processes are, by regulation, to be partially open to the public. The MOH decision processes, by contrast, have been purely internal. By international standards of open government, none of these processes appears to be sufficiently open – based on comments by stakeholders and an examination of regulatory provisions giving decision-makers broad discretion in keeping aspects of the process closed.

The PDL selection process is the most open. Sessions are normally required to be open, and are to be announced to committee members and invitees (applicant firms) at least three days in advance. Applicants can make 10-minute presentations. While some degree of openness is to be applauded, the restrictions are in fact quite severe. Note, first, that only those invited (generally firms with pending applications) can attend – this excludes the general public, notably researchers, advocacy groups, and journalists who may wish to understand or participate in the process from a public interest perspective. Second, the regulation allows the Commission Chair to decide, on her/his own initiative, to keep a session closed. Third, the actual deliberations on drug selections are restricted to committee members only – but are to be documented in session minutes ("protocols"). This last restriction may sometimes be reasonable as a means to prevent undue influence or politicization of the deliberations – but much then depends on the quality of the session records (see below).

The NHIF's processes are also partially open to the public. Once the NHIF's committee has evaluated applications (contract offers) for conformity to formal requirements, applicants are invited to attend sessions in which the committee assesses price offers. Here, the bidders can discuss and adjust offer prices in response to NHIF comments. As this process was only taking place for the first time in the latter part of 2004 (i.e., after our interviews had been conducted), it was not entirely clear how it would work in practice. What is clear is that limiting attendance to commission members and bidders eliminates the potential disciplining effect that the presence of neutral observers would likely have. (NHIF has, on the other hand, put information on price offers on its website.)

As for media coverage, this is only feasible for the PDL. The media participate in a limited way; they can attend press conferences at which decisions are announced. In none of the above cases are the media, or any non-interested third parties allowed to attend sessions where applications are considered and decisions made. This has not discouraged the media from covering health and drug policy issues. A media survey covering the period June 2003-June 2004 found over 4,700 stories on this topic in the Bulgarian media (including print, broadcast, and internet). National media devoted more coverage than regional or local media, probably because the central government sets healthcare policy and drug selections (Sacheva 2004). In addition, a few Sofia-based producer and patient associations actively follow the drug selection processes – while the medical practitioners' unions are directly involved. The pressure groups of foreign manufacturers[57] continually monitor and comment on all decisions by the Positive List Commission, the NHIF, and the Ministry of Health.

Standards of best practice indicate that drug selection meetings should be open to the public, and that there should be ample media coverage to help ensure transparency and public knowledge of the processes and decisions

Rating: *poor*

5) Are selection processes documented, and are the records publicly available?

The Positive List and Transparency Commissions work according to a prior-agreed agenda (which preserves the order of application), and are required to produce minutes or "protocols" which are part of the public record – and a number of which were obtained by IHHII under APIA filings.[58] The protocols reviewed by the researchers included the selection decisions taken, but none of the discussion surrounding individual selections. Other outside observers also said that available information was not sufficient for them to determine the rationale for PDL Committee decisions.

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[57]The Association of Research-Based Pharmaceutical Manufacturers in Bulgaria and the Association of American Pharmaceutical Companies (attached to AmCham).
[58] PDL and TC session protocols were made available.

There was also some data on the number of drugs accepted and rejected, and some discussion of changes to the PDL rules. The selection decisions by NHIF are embodied in drug contracts specifying the conditions for supply of drugs by wholesalers. The contracted drugs are then entered into a list which is then ratified by the NHIF Administrative Council. In the case of the MOH, its selection process for INNs has not been documented; however, MOH makes its annual selections of trade names within those INNs under the Public Procurement Act – and the results of these are available through APIA filings.

Once again, this is a very partial form of transparency. Open government, according to best international practice, means the routine archiving of the full records of such policy-making sessions – absent a legally compelling reason to make an exception. In the case of the PDL, the researchers did obtain meeting protocols, which did not cover everything; moreover they had to go to some trouble in filing APIA requests – rather than being given automatic access to the relevant archives. It is possible that APIA practice (or the law itself) will evolve in such a way that government departments will find it in their interest to facilitate public access. In the case of the NHIF and the MOH, no such records were available – and officials from those agencies confirmed in interviews that the records would not be available to the public.[59]

Rating: *poor*

Accountability

1) Are drug selection criteria evidence-based? Are the criteria respected in practice?

Bulgarians and their foreign colleagues frequently express concern, if not outright skepticism, about this. The situation seems to become murkier as one looks more deeply into the selection system. The PDL is divided into two sections. Part A is what many would consider the Positive List proper – it lists all the INNs that are to be considered essential drugs for purposes of use in Bulgaria's state-financed healthcare system. This part purports to follow the basic criteria of an essential drug list. Drugs to be selected are those that satisfy the health needs of the public, providing effective prevention and treatment of diseases with high morbidity and prevalence, a high share in mortality and disability rates, or posing significant public health concerns.[60] Here there is no mention of cost-effectiveness as such, although it would appear difficult to construct the list without such criteria. The critical issue here is whether a compound addresses a condition that fits within the public health criteria mentioned above.

The PDL includes a second, longer list – Part B, containing specific products by trade name. These are listed, within each ATC and INN, "in descending series in compliance with the results of the pharmacoeconomic indicators analysis."[61] Thus, the trade name drugs corresponding to the INNs in Part A are listed in order, from those with the best outcomes in the pharmacoeconomic studies to those with the worst such outcomes. It is not clear from the language of the PDL decree whether drugs can be kept off the list because of a low ranking, or if they are simply listed with a low ranking (provided they fit within the INNs listed in Part A). This appears to be within the discretion of the PDLC. Interviewees stated that, for the INNs listed in Part A, all brand names for which a valid application has been submitted are included in Part B – unless they are highly expensive. Clearly, a

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[59] The NHIF list was only being updated for the first time under the new rules, and the new NFC negotiated, in late 2004. Thus, it is possible that subsequent requests under the August 2004 NHIF regulation will result in public access to such records.

[60] I.e., diseases that are contagious or affect women and children disproportionately. Decree 81, Arts. 2, 5.

[61] Decree 81, Art 2.

great deal turns on the outcome of the pharmacoeconomic analysis (see the text box in the Annex for background on this.)

In the Bulgarian context, PE analysis appears to have a more problematic role in drug selections than it does in the industrial countries. If pharmacoeconomics everywhere is in its "infancy," this is more obvious in Bulgaria, which has fewer resources and less access to the latest expertise in this area than Western countries. Further, interviewees in Bulgaria, both in and outside government, were in general agreement that PE techniques are not well-developed or used with any precision in the Bulgarian selection process. In this context, it is difficult to conclude that these analyses truly represent a disciplined, evidence-based selection tool. Worse still, there appear to be comparatively few credible PE analyses that respond directly to Bulgarian conditions. This paucity of data and resources makes it more likely that the pharmaceutical companies will play a larger role in producing these analyses than would be true in the West. The dissemination of these studies, and the spread of medical expertise and advocacy in Bulgarian civil society, is also comparatively limited. This makes a fully accountable selection process still less likely. Further, there are only uncertain indications as to whether the authorities use post-market surveillance to reconsider or delete drugs from any of the lists.

Once we move beyond the PDL to the NHIF and MOH lists, further complications arise. For the NHIF list, drugs must be on the PDL and match a list of diseases specified in regulations under the National Health Insurance Act. Also, to be selected, a drug must be reimbursed by the public health funds of at least three out of a list of eight reference countries (see above). Once drugs are identified, the NHIF Director makes a request for submissions from the producers authorized to market them in Bulgaria. The reference price for reimbursement is set, using a combination of international benchmarks and the prior year's NHIF prices (see above). Drugs are reimbursed at different levels (50%, 75%, or 100% of the reference price) depending on which categories of diseases they are used for. NHIF officials stated in interviews that these determinations require careful cost-benefit analysis of the course of treatment. Drug companies frequently criticized the methods used, in some cases suggesting that NHIF took a narrow cost-minimization approach, in other instances saying that the selections did not seem to follow any criteria except the preferences of the Ministry of Health.

The MOH list appears to use fewer such technical criteria and more political criteria. Officials said that the list is constructed on the basis of morbidity indicators, numbers of patients, and pressure from politicians and patients' groups.

International best practice provides clear guidance in this area. The inclusion of a new drug should be based on studies that confirm whether the drug is necessary for the health needs of the population, and (ideally) is cost-effective. This is particularly relevant for drugs that are not essential drugs. A transparent methodology that determines the drugs necessity for the health needs of the population and cost-effectiveness should be uniformly applied. Equally important, the deletion of a drug from the national drug formulary should be based on sound evidence that the drug is inappropriate or not cost-effective for the health needs of the population.

Rating: *poor*

2) **Are choices in the selection process explained (e.g. inclusion, exclusion, deletion)? Are these explanations publicly available?**

Best practice suggests that selection decisions should be based on clear criteria and sound evidence – and this basis should be explained and made available to the public. This is especially important where brand names are included or in the case of exclusions. In the Bulgarian case, written justifications are required to be provided to applicants, and are in principle available to the public in

government archives. There are not a large number of exclusions from the PDL, and these are said to be explained to the applicants in terms of public health and cost-effectiveness requirements. There are no particular standards applied to these explanations, and applicant firms reported that one-line explanations are sometimes offered. As stated above, expensive brand names are often excluded from the PDL. Such high-price drugs can be included, according to interviews, when the drugs in question are "blockbusters," highly effective innovative drugs with no therapeutic alternative. PDL decisions are also explained at periodic public meetings of the CPDL, with any detailed justifications provided in writing to the applicant. In the case of the NHIF and MOH lists, decisions are required to be justified for the record, but explanations are not always available to either the applicants or the public. In general, the adequacy, completeness, and ease of availability of these explanations are subject to question.

Rating: *poor*.

3) **What forms of official oversight of this process exist, in principle and in practice? How stringent are they?**

As for the CPDL, the Ministry of Health approves its decisions, and appeal is possible to the administrative courts (see below). There is, in addition, a Public Healthcare Committee in Parliament that exercises general oversight. Patients' advocacy groups and health NGOs monitor the process closely.

These same oversight mechanisms apply to the NHIF list – yet, one hears more complaints about the inconsistency or non-transparency of NHIF decisions in this area. This seems odd in light of the additional oversight mechanisms applicable to the NHIF selection process. NHIF's Control Board submits the agency's policies, proposed decision criteria, procedures, and selections to the NHIF Administrative Council and Assembly of Representatives, and finally (after review by the MOH) to the Transparency Commission established under the Council of Ministers. These special bodies are comprised mainly of policymakers in the health and drug field – and their sizes range from 37 members in the case of the NHIF Assembly of Representatives, to a membership of nine for others such as the Transparency Commission.

In addition, NHIF is subject to audit, for both financial and technical performance. We discussed the findings of recent audits previously. One finding relevant to the present discussion was that oversight by the NHIF Control Board was generally inadequate and formalistic. The Board did not make use of the powers at its disposal. It was not helped in this by the lack of a unified information system and adequate staff for monitoring.

The above finding fits with interviews in which firms and outside observers said that these NHIF selection bodies were "on the same team" as the Ministry of Health – i.e. politically subordinate. Such statements do not prove malfeasance. But they do point out that the formal checks on selection decisions have only a weak basis, can be overridden, and hence pose little real obstacle to political manipulation. Decisions on the MOH Expensive Drugs List are even less open and more within the policy discretion of the Minister and his officials.

International experience shows that selections are best made by an independent commission of professionals that is subject to effective oversight by some combination of the public, the health professions, the courts (administrative law review), the supreme audit agency, and parliament.

Rating: *poor*

4) **In what ways can the public provide input to these processes, e.g. applications, appeals, review and comment on proposed rules?**

The PDL and the NHIF list are compiled on the basis of applications by drug producing firms – in the latter case including documentation that designated wholesale dealers are part of the submission and stand ready to supply the medicines. The MOH uses no such process for the Expensive Drugs List. For both the PDL and NHIF list, rejections can be appealed within three days, to the MOH. NHIF and BDA can submit applications for inclusion of drugs on, or exclusion of drugs from, the PDL. Officials described the PDL selection process as open to public input, citing submissions and comments by experts, physicians' and patients' groups, companies, and others. Parliament and the media take an active interest. Only the PDL process seemed to provide reliably for public notice and comment – and this only during a very brief 3-day window. No such comment period is provided in the NHIF or MOH processes.

There seemed to be agreement among many observers that the PDL process was not manipulated by any specific interests – except that foreign producers believed the selection criteria were biased to favor domestic industry. The NHIF and MOH listing processes are said to be less open, and are (partly as a result) more frequently criticized as being biased or corrupt. This is a natural outgrowth of the discretionary, ministerial character of these two processes, which are therefore less restrained by legal standards and control processes. Adverse perceptions were also inevitable, based on the ad hoc way in which the NHIF list was managed, at least through 2003. The minutes of PDL Commission meetings reflect members' concerns about the feedback they had received from applicants – mainly criticism of hurriedly produced application forms (without industry comment) and the extremely tight timetable for submission of applications (24 days after forms were released). Vocal criticism was also heard about the content of the lists. The associations of foreign drug producers became sufficiently concerned about the processes that they filed lawsuits (see the text box below) besides issuing numerous letters, position papers, and broadsides.

Good practice suggests that open and formal consultations with the public should be institutionalized to ensure all stakeholder views are taken into account in the drug selection process and in its aftermath and that no one group has undue influence.

Rating: *poor.*

Prevention

1) **How and by whom are drug selection officials appointed? How long is their tenure?**

Best practice internationally suggests that an independent body should be responsible for the monitoring of drug policy decisions. This institution should undertake regular audits and issue publicly accessible reports.

According to Decree 81, the members of the Positive List Commission are nominated by the MOH and approved by the Council of Ministers. Members should be scientific specialists on pharmaceuticals and their use. The CPDL Chair, appointed by the MOH, has no voting rights. Officials reported that the Commission must have three members from the MOH (and no representatives from the industry). The term of office is not fixed, nor is there a rotation policy – members can be replaced at any time, with the same appointment process. The Commission depends on outside experts, who conduct analyses and provide reports, but have no voting rights. There is also an administrative staff, supplied by the MOH.

NHIF combines drug selection and contracting for supplies in its listing process. Four distinct committees handle, respectively, drug specification, setting reimbursement prices, developing contract documentation, and contract negotiation. These committees are ad hoc (having no fixed term), and are required by regulation to include relevant experts – or, in the case of the contract committee, to be comprised in equal part of personnel named by NHIF and by the Medical and Dental Associations. NHIF decisions are reviewed by the Transparency Commission, whose members are chosen by the Council of Ministers, and include representatives of the MOH, NHIF, and Bulgarian Drug Agency. The MOH listing process is handled by MOH officials appointed by the Minister to annual terms, renewable.

In summary, the committees are staffed and overseen by the MOH – a situation that does little to ensure independence from a Ministry that has often been criticized for political intrusion and corruption. This is most obvious in the cases of the NHIF and MOH committees. This is less clear with regard to the CPDL, but outside interviewees felt that its members were "on the same team" as the MOH – and in any case, the only check on MOH selections by law is approval by the Council of Ministers. Also of concern here is the lack of fixed terms or rotations – CPDL members can be replaced at any time by a joint MOH-Council of Ministers decision. The Transparency Commission has a slightly better claim to being independent of the MOH (in principle, but less clearly in practice), given that it is chosen by the Council of Ministers from several agencies. This and the increasing political scrutiny of drug policy decisions points to the possibility of greater accountability and integrity in future.

Rating: *average*.

2) **Do the committees and officials who make selections have the appropriate mix of skills? Are they neutral, or do they represent a balance of stakeholder interests?**

The record here is uneven. There are no requirements or practices ensuring balance on the PDL Commission, in terms of either qualifications or representation. In particular, there were (at the time the research was conducted) no economists or quantitative experts among the Commission's regular members despite the fact that officials emphasized the importance of pharmacoeconomics to its decision making. The Chair was an expert on internal medicine and clinical pharmacology. The makeup of the MOH selection group is drawn from the Ministry, although officials reported that it included those with expertise in pharmacology, law, and economics. The NHIF committees, as discussed above, are subject to some (limited) requirements in terms of skill-sets and representativeness. An economist serving as Deputy Minister of Finance has been the chair of the NHIF Management Board and also a member of the Transparency Commission.

Generally, little effort is made toward ensuring wide representation on these commissions, and there are questions as to whether the right mix of skills is included. This situation, with the relative scarcity of public scrutiny, does not give us confidence that the commissions act on an independent, professional basis to take the breadth of social and technical issues into account.

A large number of outside experts are brought into these processes to provide analysis – CPDL members reported using some 140 of them. This could potentially lend greater professional and political credibility to the processes. However, this is strongly counterbalanced by the fact that sophisticated analyses, particularly in the field of pharmacoeconomics, are mainly the province of large drug firms. At least in the Bulgarian context, it is only the companies that can usually afford to carry out such studies (they are said to offer these studies to the government on a "good will" basis). These studies are probably not based on impartial pharmacoeconomic models but more likely models that tend to have favorable outcomes.

According to best practices, names of selection committee members and their qualifications should be public information and listed in the formulary manual and on a government website. The justification and method of appointment should also be clearly stated and publicly available

Rating: *poor*

3) **What other occupations and activities are selection officials involved in – including active medical practice? Do the rules require the declaration, or at least the avoidance, of possible conflicts of interest? Are there limits to officials' contacts with drug companies?**

Members of the PDL, NHIF, and MOH committees include government officials, hospital managers, university professors, researchers, consultants, or medical practitioners. Many of the experts serving these committees are medical practitioners or researchers, and are frequently involved in clinical drug trials which are a clear conflict of interest.

In Bulgaria, the community of specialized experts – especially those who are able to analyze particular classes of drugs – is small in number. In such a situation, strongly restrictive rules on permissible activities by commission members and experts may be impractical but the system should at least ensure disclosure of potential conflicts of interest. Bulgaria prohibits direct participation (or close relationship to a direct participant) in drug manufacturing activity. However, it is questionable how effectively this is enforced.

The officials who deliberate on drug choices for the PDL, NHIF list, and MOH list are largely civil servants drawn from the Ministry of Health, NHIF, and others. The Bulgarian Civil Servants Act and Civil Servants Code of Conduct provide the basic ethical standards here. Officials are not obliged to be involved in any decisions that may involve conflicts of interest (for the official or her/his relations), and they should not do so. The civil servant is required annually to declare economic interests (personal and familial) that may have a connection to her/his administrative functions. The official also has an affirmative duty to call potential conflicts to the attention of superior officials and to clarify any issues.[62] Certain senior officials are subject to a more comprehensive asset declaration requirement.

Sector-specific regulations reinforce these basic ethical principles in the drug selection context. Officials cited two broad provisions on this issue, from the Law on Drugs and Human Medicines, and Decision no. 13 of the MOH, both of which prohibit officials (on specialized authorization and advertising commissions, not the selection bodies) from benefiting materially from their positions. We also identified a more specific provision, which prohibits drug selection commission members, and experts working with these commissions, from accepting honoraria and expenses from companies sponsoring meetings and symposia.[63]

The drug selection regulations also provide for disclosures and procedures in case of potential conflicts of interest. The PDL Ordinance states that the chair and members of the CPDL are required to keep all information from Commission proceedings confidential, and "should not participate in activities related to manufacture or wholesale trade with pharmaceuticals" (Art 10). The PDL has

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[62] Civil Servants Act amendments, State Gazette no. 70, August 1, 2004; Civil Servants Code of Conduct, State Gazette no. 53, June 22, 2004.
[63] Regulation 13, 14-7-2000, on conditions and approval of advertisements of medicinal products; published in State Gazette no. 59, 21-7-2000 and amended 15-7-2003, State Gazette no. 63.

developed its own "Non-Conflict of Interest Declaration" (obtained by APIA request), which simply asks for a list of contacts with drug producers, wholesalers, and other organizations working in the relevant field, and for the declarant's signature on a short statement that she/he will keep the proceedings confidential and is not "participating in activities with producers or wholesalers of drugs." The NHIF regulations require members of the NHIF's contracting commission to declare that they have no commercial relationships to drug producers or distributors. Transparency Commission members are also subject to a confidentiality requirement.

These provisions are not well developed. A comprehensive declaration of assets is rarely required – usually only a declaration is needed, subject to the official's interpretation, of probable conflicts is required. Further, we found no evidence of that conflict-of-interest declarations are required to be independently verified. Lastly, only civil servant members of these commissions appear to be legally required to sign declarations – the many outside experts that interact with the commissions do not appear to have any such obligation (although experts are prohibited by law from accepting material benefits offered by drug producers). More elaborate declarations and oversight might be deemed too costly in the Bulgarian context, but the cost of this is that the information base for detecting conflicts and related problems is very slight.

Significant reforms are needed to minimize the likelihood of conflict of interest in drug policy making – these are discussed in the concluding section of this report. As practice in Bulgaria evolves and problems are addressed in this area, one would expect the provisions to be further fleshed out. The text box below offers some potentially useful lessons from the U.S. experience in this area.

Rating: *poor*

> 4) **Are drug-selection procedures conducted regularly, or are there delays between sessions?**

The Positive List decree requires the Commission to meet at least once per month and also requires the PDL to be updated annually. Officials and outsiders suggested that the meetings are not as regular as this, since during some months there are only a few applications pending. The fact that the PDL is updated once per year creates problems. Its deadline for applications to the updated list does not coincide with potentially lengthy processes of approval by the BDA and others.

Delays arise from the sequential nature of the approval steps, the lack of predictable time-limits (i.e. the agencies can exceed the maximum delay with impunity), and the lack of synchronicity among the steps. For example, it seems to be common for the completion of one step (e.g. price registration) to occur too late for the next one (e.g. Positive List) to proceed – and so up to a year is lost in waiting for the next round (interviews with pharmaceutical producer associations). As a result, the process can require some applicants wait two to three years from the time they begin the process at the BDA until the products can be prescribed and reimbursed. This intensifies the pressure for companies to do everything necessary in order to get timely approval – and where oversight of officials involved in the process is not robust, this situation creates significant corruption risks.

The NHIF uses ad hoc procedures that occur in advance of the annual negotiation of the National Framework Contract. Transparency Commission meetings are required to be held at least once in two months, in order to oversee the NHIF's procedures. The MOH committee convenes during the first quarter of the year.

Ideally, these time lines would all be coordinated, clearly communicated to all, and respected. This would promote transparency and discourage efforts to manipulate the processes. Global experience

shows that delays often encourage informal deals, including expedited processing in return for bribes. In other fields where multiple regulatory regimes apply, some of these problems have been addressed through the establishment of "one-stop shops" and the harmonization of data and formats used in applications. In any event, each institution involved in drug selection should be obliged to have a regular schedule.

Rating: *average*

5) **What methods are used to make selections, e.g. unanimous decision, majority vote, choice by individual official? Are decisions vulnerable to political influence – and how is this addressed?**

The PDL Commission makes decisions by a ¾ supermajority of members present (with a quorum requirement of ¾ of members). NHIF and TC decisions are determined by majority vote of those present, provided that at least half of the members are present. CPDL and NHIF decisions are required by law to be "motivated" or justified. The MOH does not follow a fixed voting procedure, but reaches decisions through deliberation. As noted earlier, the MOH appears to exert decisive influence on these decision processes, with the possible exception of those taken by the Transparency Commission. In a policy context such as this one, where official decisions allocate major shares of product markets, greater formality of decision-making is probably justified, along with independent scrutiny of compliance with voting procedures.

Experience suggests that the decision making process for drug selection should reflect input from a number of individuals and not be made, de facto, by one person. Information should be published on the processes and procedures, and the individuals responsible for them at each stage of the drug selection process. The rationale for drug selection should be clearly presented and backed up with the appropriate scientific and economic justifications.

Rating: *poor*

6) **Can interested firms influence the selection process? What methods do they use – e.g. policy arguments, education and promotion, meetings with relevant officials, favors?**

There is a widespread belief that pharmaceutical companies use lobbying, influence over drug studies and information, exchange of favors, and bid-rigging to secure their shares of these quasi-public drug markets. Indeed, one of the international producer associations alleged that the design of the PDL itself resulted from lobbying by the domestic industry in Bulgaria and that it effectively prevents market competition from international producers. Given the prevalence of imports on all the lists, this charge seems implausible. Interviewees suggested two competing influences on the level of lobbying and corruption in this area – first, the need for domestic firms to win sales before quality standards change and the market opens up as a result of EU accession in 2007, and second, the introduction of international price guidelines into the NHIF process, which should help constrain price-setting discretion and reduce prices.[64]

To mitigate this influence, anti-bribery laws, and political campaign finance norms are relevant. In principle and in practice, both of these sets of rules are weak in the Bulgarian context (OSI 2002). Interviews suggest that drug company representatives are able to meet informally and on an individual basis with selection commission members. Bulgaria's conflict-of-interest norms do not

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[64] Still, there are charges that, for example, unfair competition in vaccine tenders resulted in Hepatitis B vaccine prices that were ten times those in the Czech Republic.

prohibit this. More pervasive are drug company contacts with physicians (common globally), whether in the form of industry-sponsored seminars and conferences, studies, advertising, or direct marketing. Since physicians make up a large proportion of commission members and experts, companies are likely able to exert "back door" influence on the commissions with little hindrance.

There are also industry-based ethical codes – a short review of major examples is presented in the box below. In Bulgaria, standards come from several sources. According to the Association of Research-Based Pharmaceutical Manufacturers (ARPharM), these include the European Code of Practice for the Promotion of Medicines, and the equivalent Code adopted by the International Federation of Pharmaceutical Manufacturer Associations (IFPMA). These codes are less strongly prescriptive than the U.S. PhRMA Code, probably because they are transnational. However, the IFPMA Code does (unlike the U.S. PhrMA Code) outline a complaint procedure, to be handled by its headquarters in Geneva. ARPharM itself has an Ethics Committee that presumably sees to the member's adherence to ethical principles. There is no Bulgarian Code as such on this subject.

Experience globally suggests there is a need for effective controls – regulatory and voluntary – on marketing and lobbying practices by the pharmaceutical industry.

Rating: *poor*

Enforcement

1) Are the rules on official appointments and terms of reference respected in practice?

Views differ on this point. Outside observers often characterize the CPDL as being in practice subordinate to the Ministry of Health. The Supreme Administrative Court has examined if the Commission has acted within its authority. It upheld the Decree on the PDL and referred questions about the Commission's decisions to another court. This suggests that there is at least some oversight of the enforcement of drug selection policies, even if the standard of review is deferential. However, it is not clear if the CPDL's terms of reference are defined specifically enough for administrative oversight, and legal challenges, to be carried out effectively. Regular performance audits by an independent institution could ensure that appointments and terms of reference are respected in practice – so long as audit information is well disseminated.

Rating: *poor*

2) What sanctions are there for breach of the rules on conflict-of-interest, bribery and other forms of corruption?

Sanctions provided in the civil service code and the criminal law include prison terms of up to 30 years and fines up to a quarter million euros (OSI 2002). Penalties for failure to disclose conflicts of interest run from adverse reports to postponement of promotion and dismissal. Officials involved in each of the three selection processes reviewed here expressed their lack of familiarity with the sanctions provisions, and were not aware of any cases in which they were used. This, at least, suggests a lack of information and training on these points – which means that the commissions themselves are not prepared to assist in the enforcement of standards. Secondary evidence (OSI 2002) indicates that the enforcement of laws, particularly anti-corruption laws, is generally weak.

Rating: *average*

3) **Are there mechanisms in place to detect improper relationships – e.g. selection officials with undisclosed economic interests in the pharmaceutical sector, or bidding firms related to one another? Are these effective in practice, or are such relationships accepted?**

As noted, the conflict-of-interest declarations that officials and commission members are required by law to submit are not effective instruments for monitoring compliance. In addition, officials were unaware of any cases in which improper relationships were discovered and dealt with. Outside observers cited commission members with family members involved in the industry, or who were personally involved in clinical trials. Officials reported that some checking of bidders is done when there is suspicion of price-fixing. While rules exist, they are not enforced.

The government should have explicit sanctions that indicate the type of penalties that are levied on a public official if he or she has breached the law. Ideally, examples of specific cases involving these sanctions demonstrate that they are being enforced. They also serve as deterrents to others who may be contemplating breaching the law.

Rating: *poor*

Education

1) **Do selection committees or officials inform, educate, or solicit input from stakeholders?**

Public education efforts and consultations can help ensure comprehensive input into the public policy process from all stakeholders. Bulgaria does not allow for sufficient public input into its drug selection decisions – in many instances, none at all. Open and formal consultations with the public (which foster transparency) should be institutionalized to ensure that stakeholder views are taken into account in the drug selection process, and that no one group has undue influence.

Rating: *poor*

2) **How are officials trained in ethics and integrity rules? How stringent are these rules in principle and in practice?**

The committees and individuals involved in the Bulgarian drug selection processes are subject to ethical norms from different sources, including the specific rules of the relevant commission (e.g. the PDLC), the civil service code, and the members' respective codes of professional ethics. In addition, the rules of the Transparency Commission, which vets the selection criteria and processes of the NHIF, state that the TC will work according to an ethical code. When IHHII researchers requested a copy of it, the Council of Ministers office informed them that there was no such code. According to key informants interviewed, public officials are not trained on ethical standards.

Many healthcare policymakers and pharmaceutical selection committee members are physicians. As such, they belong to a profession with a long tradition of ethics and self-governance. These traditions are embodied in professional bodies and codes that are often backed up by state agencies and regulations pertaining to medical practice. In the U.S. and other Western countries, the professions operate with significant autonomy, although the extent to which they are tied to state-financed health systems (and the rules governing them) varies. Formerly communist countries have additional complications to deal with.

In Bulgaria, the relationship of the state to the medical profession has undergone dramatic change, with the high point of state governance – and the subordination of professional autonomy and ethics to state policy – occurring between 1945 and 1990. Signs that at least some limited autonomy has re-emerged in Bulgaria's medical profession include the reinstatement of the Bulgarian Medical Association (BMA) in 1990, and the incremental privatization of medical practice since then. Still, government plays a stronger role in the management of the medical profession in Bulgaria than in many Western countries.

Medical doctors in Bulgaria are subject to a Code of Professional Ethics issued by the Minister of Health, in accordance with the Act on Professional Associations of Medical Doctors and Dentists. The BMA has a Committee on Professional Ethics, which is primarily concerned with malpractice. Neither this Committee nor the Associations have shown much zeal in bringing complaints and enforcing ethical standards against physicians who engage in corrupt practices. Ethics training is not a requirement, and is not regularly available to physicians in Bulgaria. The box below discusses some of the difficulties posed when professional ethics standards are not sufficiently reinforced, and conflicting norms and practices have taken hold.

International experience shows that physician-industry interaction demands an effective system of monitoring and enforcement of ethical standards, with consistent interpretations of their meaning and sanctions for breaches.

Rating: *poor*

Annex 10. Integrity (TAPEE) Results for Procurement, by Hospital

TAPEE: Transparency by hospital
Non-reticent evaluation committee members

Indicator values denote increasing transparency of a scale of -1 to 1

TAPEE: Accountability by hospital
Non-reticent evaluation committee members

Indicator values denote increasing accountability of a scale of -1 to 1

TAPEE: Prevention by hospital
Non-reticent evaluation committee members

Indicator values denote increasing prevention of a scale of -1 to 1

TAPEE: Enforcement by hospital
Non-reticent evaluation committee members

Indicator values denote increasing enforcement of a scale of -1 to 1

TAPEE: Education by hospital

Non-reticent evaluation committee members

Indicator values denote increasing education of a scale of -1 to 1

Annex 11. Regression results for hospital procurements: TAPEE and Corruption

	corrmax	TRANSP	ACCT	PREV	ENF	VALUES	reticent
corrmax	1.0000						
TRANSP	0.1297	1.0000					
	0.1447						
ACCT	-0.0176	0.1282	1.0000				
	0.8439	0.1476					
PREV	0.0093	0.1479	0.1040	1.0000			
	0.9170	0.0944	0.2408				
ENF	-0.0082	0.0975	0.6281*	0.2139*	1.0000		
	0.9266	0.2718	0.0000	0.0149			
VALUES	0.0094	-0.1305	0.0185	0.0691	0.2754*	1.0000	
	0.9159	0.1406	0.8350	0.4363	0.0016		
reticent	0.0125	-0.0271	-0.1240	0.0112	-0.1537	-0.0589	1.0000
	0.9001	0.7931	0.2286	0.9141	0.1350	0.5687	

Source	SS	df	MS
Model	1.25856389	6	.209760649
Residual	33.2858134	89	.373997904
Total	34.5443773	95	.363625024

Number of obs = 96
F(6, 89) = 0.56
Prob > F = 0.7603
R-squared = 0.0364
Adj R-squared = -0.0285
Root MSE = .61155

corrmax	Coef.	Std. Err.	t	P>|t|	[95% Conf. Interval]	
TRANSP	.6955308	.6208138	1.12	0.266	-.5380131	1.929075
ACCT	.2696573	.3420248	0.79	0.433	-.4099386	.9492532
PREV	.2651073	.5588424	0.47	0.636	-.8453006	1.375515
ENF	-.3046727	.2408355	-1.27	0.209	-.7832076	.1738623
VALUES	.0417295	.3403731	0.12	0.903	-.6345846	.7180436
reticent	.0174205	.0893111	0.20	0.846	-.1600387	.1948796
_cons	2.390498	.3163284	7.56	0.000	1.76196	3.019036

Source	SS	df	MS
Model	.486707006	4	.121676752
Residual	34.0576703	91	.374260113
Total	34.5443773	95	.363625024

Number of obs = 96
F(4, 91) = 0.33
Prob > F = 0.8605
R-squared = 0.0141
Adj R-squared = -0.0292
Root MSE = .61177

corrmax	Coef.	Std. Err.	t	P>|t|	[95% Conf. Interval]	
TAP	1.813554	3.887345	0.47	0.642	-5.908178	9.535287
ENF	-.1752534	.1922568	-0.91	0.364	-.5571479	.2066411
VALUES	-.1017153	.3223072	-0.32	0.753	-.7419389	.5385084
reticent	.0164763	.089362	0.18	0.854	-.1610303	.1939828
_cons	2.735618	.1738743	15.73	0.000	2.390238	3.080998