

PHARMACEUTICAL MARKETS: PUBLIC AND PRIVATE ROLES AND FAILURES

Prof. Dr Ec. Sc. Stefka Koeva

It would be difficult to neglect or underestimate the importance of the pharmaceutical markets. On the one hand, the progress in pharmaceuticals has had a dramatic effect on reducing mortality and illness rates and increasing life expectancy. On the other, the general cost of medicine intake is impressive. For example, the sale of pharmaceutical products in Bulgaria's general health costs represents 41%¹.

Pharmaceutical markets are different from all other product markets. Although they have some characteristics in common with the health and medical service markets – which are quite specific in their own right, there are a number of differences even among these related spheres. The following article adopts the viewpoint of economics theory to present the need for impartial treatment of the market and the state as simply two distinct mechanisms (or a collection of rules and institutions) for interactions between individuals in order to fulfill specific goals in production, distribution, supply and use of pharmaceutical goods. The purpose of this approach is to contradict the unreasonable but persistent in economics literature and political thought view that one type of markets (or mechanisms) – private ones – have a number of faults and failures, and therefore, the other type – public (or political ones) are a cure-all for each issue. Our argument instead follows the logic that both types of mechanisms and markets, private and political, apart from their benefits (which fall outside the scope of this article), have some serious failures (faults), and it is this complex overview that should be taken into account when designing appropriate policies.

The article is structured on the following principle. First, we would analyze the peculiarities of pharmaceutical markets exchange. Then, we would briefly describe their complex structure; identify the stakeholders and their roles. The final part deals with issues in terms of efficiency both in private markets and their regulatory centre – the state.

1. Characteristics of pharmaceutical markets exchange

There are a number of specifics concerning the exchange in pharmaceutical markets which mark the whole nature of these markets:

- The objects of exchange are drugs, which in terms of their uses, are specialty goods. Each medicine is a powerful chemically or biologically active product with a clearly defined pharmacology and toxicology. Given that one follows the directions for use responsibly, it could save a life or improve health, but in case of negligence, it may not only harm the patient but actually lead to a fatal end.

¹ IFPMA. The Pharmaceutical Industry and Global Health. Facts and Figures 2012. http://www.ifpma.org/fileadmin/content/Publication/2013/IFPMA_Facts_And_Figures_2012_LowResSinglePage.pdf

- *The patient is not a customer in the traditional sense.* In the case of pharmaceuticals, there is a breach of a major assumption in economics – that of the autonomy and sovereignty of the customer in an exchange. The incapacity of the patient as a customer has several aspects. First of all, the choice of a given medicine often does not lie with him/her, it is predetermined by the doctor or the pharmacist. The medicine's effect depends on a wide range of factors: the health state of the patient, contraindications, side effects, interactions with other drugs used, method of administering and dosage, age, health habits etc., therefore the customer/client is quite incompetent (or at least not properly informed) to make a decision about the transaction. He or she is not in a position to make an educated choice between alternatives. Besides, the patient may not be able to evaluate the possible effects of not taking the medicine. By purchasing a given medicine, he or she does not acquire an 'asset' that they could then dispose of in any way they like. In terms of the patient's incapacity, pharmaceutical markets have a lot in common with health markets, but in this case the informational disparity has additional aspects and includes an additional 'actor', the pharmacist (manufacturer, vendor etc.). In fact, even a common doctor or a pharmacist may not be competent enough to assess the safety, quality and efficacy of the product.
- Both the information flow and the decision making are quite peculiar to the pharmaceutical markets. However, the *payment aspect*, similarly to health markets as a whole, defines the *specific demand structure*. In many cases the payer is a third party – the insurer, who has their complex and multilayered motivation: clinical, health-economical, financial, political etc. The fact that the medical professional acts both as the patient's agent but also as a 'gatekeeper' to the pharmaceutical market, without paying for the medicine, and often not knowing or not caring about the costs to the patient or the third party – the insurer, makes the price elasticity of demand considerably lower. What that means is, in practice, prices do not fulfil their key market function – the signalling function that guarantees the distributional efficiency. The transmission of information signals to stimulate adequate economic behavior is hindered, and sometimes completely distorted. Such an effect is additionally compounded by the fact that the middleman (agent) could be influenced by a number of factors when making a choice, as far as he/she has a vested interest (e.g. pharmaceutical promotions). Caution or the natural worry of being ill makes patients choose or try to pressure their doctors into prescribing expensive medicines, when it could be the case that cheaper or no medicines at all could be the more appropriate solution. Besides, patients' behavior is definitely influenced by their role in paying for a particular treatment.

The complex motives and considerations of all three parties in the transaction are shown in Table 1.

Table 1**Medicines purchase – decision making participants**

<i>Decision maker</i>	<i>Decision Regarding</i>	<i>Possible motives for the decision</i>
Payer (insurer)	Whether to reimburse the medicine purchase	Priority of the condition
		Needs (un)fulfillment
		Budgetary considerations
		Health-economic considerations
		Political motives
		Demand/pressure by prescribing doctors
		Demand/pressure by patients
		Personal considerations of the payer
Doctor (the prescriber)	Whether to prescribe the medicine	Professional considerations
		Financial interest of the patient
		Financial interest of the doctor
Patient	Whether to purchase the prescription	Doctor's advice
		Expected effect on health status and quality of life
		Amount paid by the patient (with a proportion paid by the insurer)
		Price – when paid directly out of pocket

Based on: Gregson, N, et al. *Pricing Medicines: Theory and Practice, Challenges and Opportunities*. Nature, Vol. 4, February 2005.

- *Medicines* (similar to all health services) *have a dual character as economic goods*². They may have the characteristics of *consumer goods*, to carry immediate usefulness so that the patient feels instant gratification upon their intake. However, in the majority of cases, they are more of *investment goods*. The patient would gain or return his investment at a future point, or may never benefit at all. Additionally, there is a considerable percentage of uncertainty, which marks the normal action of market forces. The patient may be unable to judge for themselves whether to take a certain drug (for high cholesterol, for example) (that is, to invest), or not to take it (not to invest). He/she must take into consideration the possible benefits of prevention of potential harm and illness before experiencing it, which is practically impossible.
- *The decision to use or not a certain medicine could be irreversible.*
- A particular aspect, although rather more regulatory than economic, is the *community engagement with the issue of equity and equitable access* in transactions of this sort. The considerations may be ethical and pragmatic, but they mark the way the sector functions.

² Grossman, M. "On the Concept of Health Capital and the Demand for Health". *Journal of Political Economy*, 1972, 80(2), 223-255.

2. Structure, stakeholders and their roles

It is largely due to the above-mentioned characteristics that pharmaceutical markets have evolved and reached their current state of complex, heterogeneous structures with a large number of stakeholders and varying proportions of private and public subsystems. It could, however, be argued that state participation and interference with the pharmaceutical market is much more widespread and systematic than usual. Decomposing the pharmaceutical market allows us to single out several subsystems according to their phases and functions in the overall production and distribution process till the endpoint – the customer; it also allows us to identify the stakeholders or “actors”³ involved in these subsystems. Due to format constraints, this article will only outline the stakeholders inasmuch as this will support the main argument.

- *Drug development* – the stakeholders in this phase could be either **private** – pharmaceutical companies, or **public** – state-owned research institutes and laboratories, state universities, state grants etc. Often at this stage, as well as in a number of others, a variety of **private institutions** are also involved, such as private universities or **non-for-profit organisations** – foundations and research institutes.
- *Drug registration and regulation* - usually the state, through its executive bodies, controls the entry to the market of various medical products – new, generic and over-the-counter drugs (In Bulgaria this is a function of the Bulgarian Drug Agency, in the States it's the U.S. Food and Drug Administration and so on). **Private agents** can participate at this stage through contracts for drug quality testing.
- *Drug manufacture/import* – this is mostly the domain of **private companies** (local or branches of multinational corporations), but **the state** could also own its production facilities, import plants or wholesale stores.
- *Wholesale drug distribution* – once again both **private** agents – wholesale drug merchants and **public** institutions are involved. The state participates through licensing and regulation of private businesses.
- *Drug prescription/supply/sales* - **private** stakeholders are private hospitals, clinics, pharmacies etc., while **the state** is also an active participant in this phase with its hospitals, clinics, dispensaries, pharmacies etc. It subsidizes drugs for certain groups and has an active role in educating and licensing medical practitioners (pharmacists, doctors etc.), as well as in establishing and enforcing a code of practice.
- *Drug information supply* – **the state** plays a major role in forming the standards and requirements for drug information, it educates health practitioners, patients and society as a whole, while **private** market actors produce and disseminate this information.
- *Final drug consumption* naturally rests with *individual consumers/patients*, who are *the final market stakeholder*.

³ After Bennett, S., J.D Quick, G. Velasquez. *Public-Private Roles in the Pharmaceutical Sector: Implications for Equitable Access and Rational Drug Use*. WHO, 1997.

On the whole, it could be argued that the state, as an embodiment of the public, forms, enforces and controls the national drug policy through its legislative branch and the corresponding health ministry, as well as other ministries and bodies. For their own part, private stakeholders – manufacturers, importers and providers, as well as professional associations, patients' organisations, consumer organisations etc. are all influenced by and in turn actively influence these policies and institutions.

3. Efficient resource use failures

What causes this overwhelmingly complex structure of the pharmaceutical markets? Standard economic theory gives a standard answer: a series of market failures to ensure the efficient resource allocation, with either too much or too little being produced, and the possibility that some goods may not be produced at all. That is why the other major stakeholder – the state, has so many roles. However, it would be too simplistic to blame the markets for all the issues with the pharmaceutical sector. (We would then be making the same mistake as the unreasonable ruler who once held a contest between two singers in order to decide who was more talented. After hearing the first performance, he simply awarded the prize to the second one, without even wanting to test his abilities. Obviously, the chances of him having the same faults were equal, if not higher. I owe this wonderful analogy to Boettke⁴ [3]). Unfortunately, we have been constantly reminded of the fact that the state is just as susceptible to failures and faults, and these could be called 'political failures'. Once again, due to text limits we would only outline some of the failures of the two main stakeholders in the pharmaceutical markets.

Market failures:

1. *Asymmetric information.* On the whole, manufacturers, sellers and consumers of common goods are usually equally aware of the quality and efficacy of the products. If, however, one party knows more than another, the markets could produce suboptimal results, i.e. fail. Similar to health markets in general, here the patient is quite disadvantaged with regards to information access. Depending on the nature and time frame for accessing quality information, goods could be classified as *search goods* – products whose quality could be verified prior to purchase (e.g. a coat that one is about to buy), *experience goods* – products whose quality can only be established upon experience (e.g. a new wine one is about to try out), and *credence goods* – whose quality can only be confirmed after additional expenditure (either informational or other)⁵.

The majority of drugs fall under the third category. It takes time to verify their quality, efficacy and safety. In some cases, they may share some of the characteristics of the second type, where the efficiency is easily established, especially through widespread use (e.g. cold medicines or Viagra). However, for most medicine products the desired effect is far from immediate and that makes it harder to make an assessment.

⁴ Boettke, P., C. Coyne. "James M. Buchanan (1919–)". *Dictionary of Modern American Philosophers*. J. R. Shook, General Editor. Thoemmes Press, 2005, pp. 373-377.

⁵ Nelson, P. "Information and Consumer Behavior", *Journal of Political Economy*, 1970, p. 311–312; Darby M. R., E. Karni "Free Competition and the Optimal Amount of Fraud", *Journal of Law and Economics*, 1973, pp. 67, 69.

Not to mention the difficulties in evaluating long-term effects, possible complications etc. Even if he/she could afford it financially, the patient cannot randomly try out and turn down drugs, as this might be harmful or even fatal for their health. In other words, the patient needs to know the drug would work. This informational imbalance between patient and doctor allows the latter to possibly act in their own interest, which is an inherent trait of health markets as a whole.

In the case of pharmaceutical markets, however, there are additional substantial informational differences between stakeholders. As the effect of a given drug would vary depending on the patient, it is only through large-scale research samples and careful application of statistical methods that significant information can be gathered. This is not only far beyond the abilities of a single patient who remains totally and painfully ignorant, but could be out of reach for even the best medical specialist. Lack of knowledge in the prescribing subject (the doctor) could once again lead to a suboptimal solution to the problem. The manufacturers (pharmaceutical companies) and distributors have an overwhelming informational advantage and could manipulate the situation in order to obtain the best financial results. Asymmetric information, which causes the market failure of health markets, plays *an even bigger and more active role here*. The state's counteractions against such a failure are various: promotional practice regulations; establishing of standards and requirements for drug information, as well as monitoring their observance; educational campaigns for health practitioners, patients and society as a whole, etc.

2. Pharmaceutical markets illustrate another classic example of market failure - *externalities* through control and treatment of infectious disease such as tuberculosis and HIV/AIDS, and their prevention through vaccines and immunization. Since both treated and vaccinated patients note only the immediate private benefit of disease prevention, but not the wider social benefit of protecting others, the market can lead to a level of immunization and treatment which falls below the socially optimal. The state balances this process out through subsidies. By lowering the prices for consumers, it helps to increase drug use and encourage treatment. Through buying vaccines and/or arranging vaccinations, the state acts to fill in the gap left by the market till the socially acceptable result is reached.

3. Some functions of the pharmaceutical market have the characteristics of public goods. Those are collectively consumed goods. Due to their specific nature, public goods are *non-exclusive*, that is they cannot be offered to an individual without everybody else having access to them, and they are *non-rivalrous*, the use by one individual does not make them unavailable to others which means that the marginal cost to every subsequent consumer is zero. Therefore, the market fails to monetize their value and this holds the possibility for such goods to not be produced in the first place. For example *safety testing of drugs* may have the nature of a public good. Once 'produced', such an evaluation can be freely used by all others, even if they have not contributed (by co-financing the rather costly testing process). In other words, the free rider's problem is extremely topical in this stage of the pharmaceutical process. If left on its own, the market may not produce a similar safety evaluation, and the public organ is called upon to right the market failure.

4. *The barriers to entering the market* are an important trait of drug supply, which creates a tendency towards a monopoly of the market, and therefore, inefficiency. A main barrier here is *patents* as a monopoly right given to the drug manufacturer to be a sole manufacturer for a certain period (20 years), which guarantees the innovator high return and stimulates risky and costly, but socially valuable, research projects. Of course, there are multiple levels of monopoly market power. It is strongest with patented, innovative, major drugs, for which there is no alternative medicine or an intervention, so-called *single source medicines* (a classic example would be Herceptin for breast cancer), and for which demand is highly inelastic. But even in this case the monopoly power is not limitless and it could be counteracted (through buyer monopsony, when an institution such as the National Health Insurance Fund, NHIF, buys on behalf of all users; through state price regulation mechanisms, etc.)

State Failures (political failures)

1. A possible failure (suboptimal result) due to *personal interest of the approval body for new drugs* stems from the uncertainty and lack of knowledge over the efficacy and safety of each new medicine. Such an uncertainty may cause the drug approval body to commit two types of mistakes⁶: *type 1 mistake* – to reject a medicine, which is safe and effective; *type 2 mistake* – to approve a medicine, which is not safe and/or ineffective. Obviously, both types affect patients' health and well-being, whether we are talking about legalizing a 'bad' medicine, or discarding a 'good' one.

The free (unregulated) market supposes the motivation for *type 2 mistakes* - a manufacturer is always interested to reap the benefits of a new drug. On the other hand, where there is regulation, the state (the regulating body) has *its own motivation*: 1) In case of a 'bad' medicine approval (type 2 mistake), the remedy cost is too high and the failure is too obvious – losing posts, public scandals etc.; 2) When a 'good' medicine is discarded (type 1 mistake), however, the cost is borne by a third party (manufacturers and patients) and is rather less visible. Therefore, the state agency has a motive to make type 1 mistakes – to deny permission or to at least slow down the process of approval. A number of empirical studies⁷ show that the regulatory effect on 'new chemical entities', that is, the imposed requirement for companies to demonstrate the efficacy of new drugs and the over-cautious attitude of the States' Federal Drug Agency, is to considerably slow down the introduction of new medicines without any perceptible improvements in quality. As a result, the drugs which eventually get approved for sale, reach the market a couple of years later than the same medicines sold in the UK, for example. The result is comparable to imposing a 5-10% tax on all drug purchase during the 70s and 80s and has led to the loss of thousands of lives.

⁶ Grabowski, H. G., J.M. Vernon. *The Regulation of Pharmaceuticals: Balancing the Benefits and Risks*. Washington, D.C. American Enterprise Institute, 1983.

⁷ Peltzman, S. "An Evaluation of Consumer Protection Legislation: 1962 Drug Amendments", *JPE*, September/October 1973; Grabowski, H. G. "Regulation and the International Diffusion of Pharmaceuticals", in R. B. Helms editor, *The International Supply of Medicines*, American Enterprise Institute, Washington DC, 1980; 8. Wiggins, S. N., "Product Quality Regulation and New Drug Introductions: Some New Evidence from the 1970s," *Review of Economics and Statistics*, Vol. 63, Nov. 1981, pp. 615-619.

2. Another possible failure is linked to *formulating and implementing the pharmaceutical policy*. Such a failure would be a function of the whole political system and its operations: legislative and executive, party configurations and programmes, susceptibility to group interests⁸. The failure may be due to relationships with powerful interested individuals, or just to a limited capacity, etc. In the Bulgarian context, it is the Bulgarian Drug Agency that controls the registration, import and production of medicines, as well as clinical tests, wholesale and retail of drugs and their advertising. In practice, however, just a handful of inspectors are responsible for the whole process of control nationally, which is partly the reason behind the agency's notoriously ponderous reactions.

A special mention needs to be made of the unstable management of the health system and its pharmaceutical segment, the inconsistency and lack of logic behind a large proportion of all decisions. Here we can mention two examples that are highly indicative of this trend. The first is the idea (gone unrealized) of a previous government to relocate the drug regulating body from Sofia to Pleven. The other one is the non-market limit for patients and prescriptions imposed on pharmacies, a measure later ruled out by the Commission for Protection of Competition. Furthermore, the executives who are responsible for the national drug policy are in fact political figures and there is a constant process of changing post holders, or at least the expectation of such changes, which further adds to the chaotic and unpredictable character of the field.

3. The short-sighted effect is the inevitable consequence of every democracy, and its negative effect is especially strong when it comes to sensitive topics, such as public health and drug policy. This effect concerns the short time span in which decisions are made by the economic circle. Private markets are more successful in sensing future effects (cost and benefit). But in political markets such effects are *largely devalued*. And the reason for this is *the relatively short electoral mandate of politicians*. Therefore, future costs and benefits are frequently underestimated (discounted), and the effects of current benefits and costs are considerably heightened. This to a large extent explains the half-hearted nature of drug policies, the numerous *ad hoc* measures and the lack of major and profound reform.

4. The state administration has its own priorities and goals, which, in a context lacking suitable institutional limits, can be an additional source of inefficiency. According to the European directive, for a clinical try-out to be initiated in Europe, the company responsible needs to present 17 documents. The corresponding requirement in Bulgaria is for over 40 documents, the collection of which would take at least 90 days, and their review – an additional 60 days. „The heavy bureaucracy, illogical requirements, delays and institutionalized nonsensical examples cause a daily clash between the state on the one side and the hospitals, doctors, patients, pharmacists and pharmaceutical companies, and all those in between.“⁹

⁸ See: Koeva, St. M. *Ikonomika na politikata: "Publichniyat izbor" – ikonomicheska teoriya na demokraciyata*. Varna, IK. STENO, 2009.

⁹ Kapital - Zdrave, may 2013.

5. Another pathology of the political markets is their *susceptibility to various groups of interests and lobbies*, which strive for their own, and not necessarily parallel to the public interest, gain. An undeniable aspect of the political process is *rent seeking*, that is individual and group actions in support of political events, which redistribute income to their benefit or to the benefit of projects sanctioned by them. Group interests may engender inefficiency as they produce substantial individual gains for a limited circle, which in turn causes small dispersed costs for a large number of individuals. In fact, pure costs for the victims may be larger than pure gain for the winners and this is socially inefficient.

The national drug policy is a striking example of such a failure. *Patients* have an undeniable interest in lower drug prices. *Local manufacturers and importers* aim for precisely the opposite. Collective action can be viewed as a type of public good being non-exclusive and non-rivalrous. If an individual decides that his/her contribution to common efforts would be negligible, yet he/she cannot be refused consumption, then he/she has all the more reason to not take action, that is, to free ride. According to market failure theory, such a line of action would lead to suboptimal production of the public good. It is mainly due to the second factor that group members are tempted to inaction, or at least, to a minimal action, therefore they are free-loaders. As a result, in some groups rational individuals would be responsible for insufficiently collective action.

The problem looks differently for the different groups, with a decisive part played by the size and coherence of the group, as well as its ability to mobilize individuals into action. For example, manufacturers lobbies are usually small, but highly focused and effective groups. As illogical as it may seem, the larger the group, the less likely it is to succeed in obtaining the optimal quantity of collective good (action), and the less effective it is in establishing the public interest. Such a group is that of consumers, who unlike the manufacturers are numerous but scattered. The *manufacturers* group is small and able to lobby, even through individual members. Patients, however, are so many, that it is impossible for an individual's efforts to be noticed. More specifically, there are several reasons for the lack of collective action. When a group grows 1) the individual member's proportion of the collective gain becomes smaller; 2) the chance for a specific community within the group, let alone a specific individual, to show initiative in obtaining the common goal is smaller, as the gain is reduced 3) organizational costs are higher, that is, the challenges that need to be overcome are bigger¹⁰. As a result, patients tend not to take action and their rational behaviour tells them to free ride. In economic terms, as each producer's or importer's lobbying actions would get noticed and would eventually influence profits, their strategic behaviour (collaboration and coordination) within the group would lead to an optimal result - pressure on the responsible state bodies. The phrase 'lobbyist pressure', which has been in wide circulation lately with regards to drug policies and price formation within NHIF, is the almost universal explanation to all conflicts within the system. Position reshuffling on

¹⁰ Olson, M. *The Logic of Collective Action: Public Goods and the Theory of Groups*. Cambridge, Mass., Harvard University Press, 1965, p. 48.

higher levels, the removal of a vice minister in connection to allegations that he was pushing through a certain manufacturer's interests, as well as yet another change of the health minister were all marked by this political pathology.

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This short analysis of the major stakeholders and principals in the pharmaceutical markets and their failures shows that the popular and conventional approach of blaming all issues and problems on market defects is unjustified. The questions that need to be asked and then answered are not who is perfect (obviously none of the singers deserves the first prize), but what we could expect from various combinations between institutions and collaborations between the two major actors (with the rising participation of civic society representatives) and which one of the limited alternatives on offer we would prefer.

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Abstract

The article presents an analysis of the specific character of pharmaceutical markets from the point of view of participating parties or "players" and the failures those suffer, in view of the efficiency of the market outcome. The proposition which is defended is that it is not only the private markets and the stakeholders participating in them, who are at times unable to ensure the efficient allocation of resources (as demonstrated successfully by standard economic theory), but also that the regulating centre, the state, too, is responsible for a series of failures and defects, which are typical of the pharmaceutical sector. The two kinds of markets, private and political, as well as their failures must be measured impartially and there must be sought the best combination in choosing a suitable policy.

Keywords: *pharmaceutical markets, market failures, political failures, interested parties.*