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Corporate Capture as a Threat to Equal Access to Medicines: a case study of Russia

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Background

Access to medicines is fundamental for people to achieve their right to health. While governments have the primary responsibility for ensuring access to health care for all their citizens, the role of the pharmaceutical industry in providing medicines carries its own responsibilities. First, companies' pursuit of strategies that address access to medicines merely as a reputational problem has resulted in patchy, ad-hoc approaches which have failed to deliver sustainable solutions. Second, the industry's responses to flagging financial performance – hiking up prices, aggressively defending patents and prolonging existing ones through 'ever-greening' rather than investing in research and development (R&D) of new medicines – have undermined needs for lower prices, flexible approaches to patenting, and R&D investment into diseases relevant to the developing world. Third, the industry's failure to comprehend access to medicines as a fundamental human right enshrined in international law, and to recognise that pharmaceutical companies have responsibilities in this context, has prevented the adoption of appropriate strategies.[i]

The concept of regulatory capture (usually associated with George Stigler) has a broad and a narrow definition. According to the broad interpretation, regulatory capture is the process through which special interests affect state intervention in any of its forms, for instance legislation affecting R&D or some quality requirements in the sphere of medicine. According to the narrow interpretation, regulatory capture is "specifically the process through which regulated monopolies end up manipulating the state agencies that are supposed to control them."[ii] Corporate capture is a more all-encompassing term than regulatory capture, because it includes all attempts by corporations to influence a decision-making process, including regulatory capture.

There are two forms of corporate capture, which Miller and Harkins (2010) call "direct" and "indirect".[iii] Direct corporate capture occurs when there is direct connection with a policy maker. Indirect capture occurs when corporations use academia, media, civil society or other stakeholders in order to influence a decision-making process. In both cases the corporate lobbyists use a wide range of methods and approaches to change or maintain current policy in order to promote their own interests.

Middle-income countries such as Brazil, Russia, India, China, and South Africa, which represent an increasing number of people with surplus incomes and untapped markets with large growth potential due to the rise in diseases afflicting both rich and poor, have been called 'pharmaemerging' economies. They are hugely attractive for 'Big Pharma'. Whereas emerging markets accounted for less than 10 per cent of global pharmaceutical sales in 2013, that figure is expected to explode to 30 per cent by 2016.[iv,v]

IMS Health predicts that pharmaceutical sales in China will increase from $65.77bn in 2011 to $143bn by 2016. Total sales in Brazil are expected to almost double from $27.69bn to $52.94bn in the same period. Sales in Russia are expected to grow by 11.5 per cent annually in the next three years to $25.4bn by 2016, while India is tipped to overtake Russia as the third biggest BRIC for pharmaceuticals, with sector revenues doubling from $13bn in 2011 to $26.3bn by 2016.[vi]

McKinsey research, referring particularly to Brazil, shows that the drug corporations are heavily focused on the middle class in pharmaemerging economies, i.e. people who rely on public services and purchase less expensive generic drugs.[vii]

In the end, these interactions between transnational companies and pharmaceutical markets are about economic power, market control and establishing dominance and thus are coupled with attempts to exert undue influence over decision making. Those with power in the health sector these days are the largest pharmaceutical giants. As the economic might of the TNCs increases, they get more power and are more able to influence the rules of the game, including trade regulations, intellectual property rights, etc. Thus, they attain more economic concentration and unlimited power. The detrimental effects of corporate capture of the health systems include, but not limited to, lack or absence of competition and lack of commitment to finance R&D (as the companies are more interested in selling already researched and developed medicines).

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[1] IMS Health data shows that in 2011 China was the third largest pharmaceutical market in the world – almost 50 per cent bigger than Germany in fourth place – while Brazil overtook the UK, Italy, Spain and Canada to take sixth spot. Russia and India enjoyed similarly impressive uplifts.

Marketing is seen by Pharma as more important than R&D

Pharmaceutical companies declare that they care about society's health and that innovative drugs have a vital role in improving human health. GlaxoSmithKline (GSK) states that "we develop and market a range of consumer health-care products based on scientific innovation."[viii] Pfizer promises "to apply science and global resources to improve health and well-being at every stage of life."[ix] These are examples of messages that pharmaceutical corporations convey to society in order to emphasize the role of science and innovation. At the same time, drug manufacturers never declare how much they spend on promoting and marketing their products. According to findings of research company GlobalData, as published by BBC, 9 out of 10 Big Pharmas (i.e. the world's largest pharmaceutical corporations, including Johnson&Johnson, Pfizer, Novartis, Roche, Merck, etc.) spend more on marketing their drugs to consumers than on research and development.[x] The biggest pharmaceutical company by revenue, Johnson&Johnson, which also has the largest marketing budget, spends more than twice as much on marketing as on R&D ($17.5bn compared with $8.2bn).[xi] The second biggest pharmaceutical giant by sales, Pfizer, spent $11.4bn on marketing and only $4.8bn on R&D.[xii]

In the USA the pharmaceutical industry measures 'innovation' in terms of new molecular entities (NMEs), but new drugs that have only minor clinical advantages may be approved by the Food and Drug Administration (FDA).[xiii] According to multiple assessments from the mid-1970s through the mid-1990s, only 11 to 15.6 per cent of NMEs provide an important therapeutic gain.[xiv] D. Light et al. argue that most R&D dollars are devoted to developing molecularly different, but therapeutically similar drugs.[xv] It is important to note that, in the last 15 years, the revenues of corporations have increased six times faster than investments in research and development.

Capture of academic research

Media capture is broadly used by the pharmaceutical corporations to influence popular attitudes and expert opinion, and to ensure the loyalty of elites.

One means of media capture is to hijack the so-called trial-journal pipeline: a corporation uses journals as a marketing tool by gathering teams of writers, researchers and editors to produce journal articles that are favourable to its drugs. Positive conclusions are published many times over in order to play up the volume of studies and to reinforce clinical guidelines for prescribing. Negative results are purposely buried and, in some instances, researchers who know these results are actually threatened.[xvi] In 2008 FDA officials carried out analysis of a registry of 74 antidepressant trials, including both trials that were published and those that were not. They found evidence that 37 out of 38 trials that reported positive results were published, while 22 of 36 trials that had negative or controversial findings were not published at all, and the other 11 were published in a way that conveyed the results as though they were positive.[xvii]

Selectively omitting negative trial results is common practice for pharmaceutical corporations. In what is perhaps the best-known case, Merck&Co concealed the fact that three patients suffered heart attacks from the drug Vioxx during clinical tests. The omissions were uncovered years later during lawsuits.[xviii] In another widely used mechanism, a corporation funds research centres, which serve as PR agencies presenting the corporation's activities in a positive light. For example, the Social Issues Research Center (SIRC), an independent non-profit organization that researches lifestyle and pharmaceutical issues, has received funding from Coca-Cola, GlaxoSmithKline and others and has failed to disclose information about a sponsor, which funded its studies.[xix]

By these means corporations capture the intellectual environment, in which public officials make policy decisions.

Capture of civil society organizations

Civil society (non-profit) organizations, such as trade unions, social movements, business associations, think tanks and charities, are supposedly defined by standing apart from the market and decision-making bodies. But corporations can create or fund 'fake' civil society organizations, which serve the narrow interests of those corporations, while pretending to serve the interests of ordinary people.

Two organizations in the USA, Freedom Works and Conservatives for Patients' Rights,[xx] claim to fight against health reform initiatives on behalf of ordinary people, but they are in fact organized by narrow and influential elite groups serving the interests of Big Pharma.

In January 2014 the South African Minister of Health presented findings about the hidden agenda of a local civil society organization, Forward South Africa. The goal of the campaign by Forward South Africa was to convince the public that a strong policy on intellectual property is good for investment and that problems of the South African health-care system were the result of failed health policy rather than patent laws and high prices for medicines.

The findings suggested that Forward South Africa had been set up with half a million US dollars funding from the Pharmaceutical Research and Manufacturers of America (PhRMA), one of the world's most powerful drug industry bodies, coordinating its action with Public Affairs Engagement (PAE), a Washington-based PR firm headed by the US Ambassador to South Africa, and with a local pharmaceutical body, the Innovative Pharmaceutical Association of South Africa (IPASA).[xxi] The consequences of revision of intellectual rights on medicines (higher standards of IP protection), as recommended by Forward South Africa, would be prohibitively high prices for medicines and inequality in access to drugs.

In many cases the pharmaceutical corporations do not conceal their role in establishing or backing local and international think tanks, but the staffing and manner of operation of these bodies is highly questionable. One example is the international think tank funded by Pfizer, the 'Pfink tank', which promotes and shares knowledge about pharmaceutical business in the context of Pfizer's own interests.[xxii] The head of the Pfizer think tank previously worked in the Reagan Administration for six years, holding senior positions. The head of the Pfizer think tank serves on the board of the Center for Medicines in the Public Interest (CMPI), which promotes pharmaceutical innovation and argues that health care is unaffordable through the public purse. The CMPI is closely associated with Pfizer and the PhRMA.

Think tanks are useful tools for the Big Pharmas because they can provide a bridge between knowledge and policy that works in the interests of the corporations.

For the Big Pharmas, capture of academia and civil society organizations serve the overall goal of policy capture.

Influence of pharmaceutical industry on policy making

There are three main factors that enable the pharmaceutical industry to significantly influence the development of government policy concerning drug supply and distribution: a high level of public corruption, inadequate legislation, and low pay for doctors. In the case of Russia, however, there is an additional factor, which is manipulation by the political elite. Rampant cronyism and corruption, rather than any improper action by the pharmaceutical companies, should rank as the first and main reason for the unequal access to drugs. The state is represented in this process by the Ministry of Health, which makes it the main purchaser of drugs from the Essential Medicines List. These drugs are purchased through a system of public procurement, which presents opportunities for corrupt activities. In addition, the state agencies are empowered to both alter legislation and monitor its implementation. Therefore, the interaction of the state and pharmaceutical companies should be considered both at the level of public procurement and the level of control over the implementation of the legislation.

Regarding the legislation, the main avenue for collusion between the government and pharmaceutical companies is created, first, by a large number of amendments to the official documents, and second, by its dynamism. This complicates the activity of pharmaceutical companies and contributes to the maintenance of very close, informal relations between them and the government agencies who regulate their activities. The reality now is that only those who are able to 'negotiate'—that is, to circumvent existing rules in some way or to use informal ways to achieve concessions in their implementation—can maintain their status on the market. Companies unable to cultivate the appropriate contacts or navigate the 'negotiation' process will find themselves, at best, shut out of procurement, and, at worst, investigated or prosecuted for 'irregularities'. While this behind-the-scenes 'negotiation' system affects all pharmaceutical companies in Russia, it can be particularly burdensome to foreign companies seeking to enter the market. They lack contacts and spend large sums of money to navigate a labyrinthine process. As one representative of the foreign pharaceutical company (anonymously) related:

> *"The overall volume of revisions and corrections to the official document exceeds the size of the original text of the regulation. And these regulations are based on a large number of sources: from the Government, the Ministry of Health, the Ministry of Industry and Trade, the Chamber of Commerce, and many other organizations. But, in general, it turns into a regulatory framework that only allows those who are helped somehow or who somehow help themselves by illegal payments to operate. (...) It is the legislation, created in Russia with unclear objectives, that leads to the fact that a foreign giant is forced to pay for coming to the country and getting started. The volume of amendments to the 61-FL already exceeds the volume of the document itself. The number of created barriers favors informal and non-transparent communication with the Ministry of Health, where the strongest wins."*

The transition to the rules of GMP (Good Manufacturing Practice) serves as an example of such complicated legislation. On the one hand, this system should ensure the quality of drugs procured by the state. On the other hand, according to the draft of the corresponding regulations act, the control of the transition will be assigned to the Ministry of Industry and Trade, with the participation of the Ministry of Health and the Federal Veterinary and Phytosanitary Surveillance. The final decision for each drug will be taken by the Ministry of Industry and Trade. Only 30 per cent of pharmaceuticals produced in Russia and circulating in the domestic market meet international quality control standards, according to the interview with David Melik-Guseynov, the Director of the Social Economy Center, and proper licensing under the new rules structure will require significant investment to come into compliance. Many drug companies will, however, be able to avoid the transition to this standard, or receive public funds to implement it, owing to their informal ties to the regulating agencies, while those who have no such links will be forced to go elsewhere:

> *"Well, here it is absolutely clear to all players in the market that the transition to GMP*

is worth a fortune, and for some companies it is more profitable simply to shut down than to borrow abroad (not in Russia!) and invest all the extra money. The rules will be unequal for everybody – close 'friends' of the government will receive preferential treatment and be allowed to ignore the GMP standards, with obliging agencies never inspecting their facilities, or will make the transition, but be supported by public money. (...) There is tremendous pressure on everybody due to the transition to new technologies and production standards. It is impossible to painlessly move to European production standards within a fixed timeframe. There is neither the time nor the means. And if the Ministry of Health or other structures introducing these requirements publicly express their hope that it is possible within such a short time, it is to remind their 'clients' that payment is expected." (Interview with the top manager of the Russian pharmaceutical company, anonymous)

Domestic pharmaceutical companies exist largely due to the largesse of the public procurement process, which involves the ministry placing a request for tenders and an open competition, where, according to the rules, the 'contestants' with the lowest bid win the contract, while meeting the required specifications. Apart from the fact that the public procurement process itself contributes to the perception that cheap, low quality drugs always win the competitions, manipulating the conditions of the tender, for example by offering to carry out deliveries in certain (compressed) terms to regions, the state creates more favorable conditions for some companies and unrealistic for others.

"The system of public procurement was consciously complicated by the state machine, there were created additional difficulties for an «unnecessary» company not to pass this global elimination. (...) To put it bluntly, the mechanisms of corrupt public procurement tenders are known for all of the participants in the market interested in a competition now. They can be arranged with sufficient accuracy. For example, in the competition they announced a requirement that the winning company would be able to deliver any drug across the country in two weeks, and obligatory at least 60 per cent of the annual volume. It is clear that this condition arose because the competition was planned by someone who had delivered the medicine in advance to regions and was awaited commands to despatch it from warehouses. All the others should produce the preparation, dilute and so forth, so they are in a very disadvantageous situation." (Interview with the top manager of the Russian pharmaceutical company, anonymous)

A public procurement system arranged in this way does not allow pharmaceutical companies to compete on the basis of the quality and availability of their products. On the contrary, it forces them to engage in battles with each other and use a variety of illegal mechanisms, including property damage,[2] fake consumer complaints, and bribery. These contests become especially intense when the tenders are for large and 'rich' regions and cities, such as Moscow, St. Petersburg and the Republic of Tatarstan. At the same time pharmaceutical companies can also influence the system, for example, by bribing competitors to drop out of the competition process, by spying out the conditions of auctions in advance and adjusting to them, and so on. In addition, the companies which have no ties to government agencies prefer not to "spoil the relationship" with larger, connected ones because otherwise the latter can simply have their Ministry friends shut them down. Small companies try to stay out of the way of the large ones, which also impacts drug procurement.

Finally, according to the interviews with the representative of the pharmaceutical companies, they can and do influence the list of medicines to be purchased by the state. The trick is that in order to participate in public procurement, a pharmaceutical company must first ensure that the medicines it produces are included in the EML. The creation of the list takes place behind the scenes, and recommendations for the inclusion of drugs are often produced by directors of subordinate research institutes, who are typically not experts on the profile of the disease for which the drug is intended. As a rule, medical researchers who test drugs to be included into the EML already have contracts with the

[2] Respondents mentioned the cases when their office (or the office of a partner company) was attacted, destroyed, including setting a property on fire.

particular pharmaceutical companies, and those companies are willing to pay for their drug being favourably recommended for inclusion. This enables the drugs produced by the company to get on the list of drugs that will be procured by the state. An renowned Russian expert on evidence-based medicine in an interview summarizes the current situation as follows:

> *"Today a new Essential Medicines List consists of 80 per cent of the junk that does not involve the patient's cure; either these are drugs which are out of use in the world for a long time, or these are drugs that have never been tested in clinical trials or these are drugs that got into the list due to the informal, but very grateful, contribution from pharmaceutical companies."*

Interaction between foreign pharmaceutical companies and the state takes on other dimensions. Firstly, as noted above, due to the dynamism and complexity of the Russian legislation, many Western pharmaceutical companies prefer to pay a bribe in order to enter the Russian market. Producers receive a large number of advantages due to careless interaction with the registration authorities that implement changes in the product documentation. For example, pharmaceutical companies which come to Russia may rewrite their indications and contraindications so as to suit the labeling requirements. It happens because *"during the registration process a lot of stakeholders at the state level are involved who want to feast, so the company, even if it does not want to pay for registration, is obliged to do so in the form of direct bribes to continue playing the market."* Secondly, the subsidiaries may pay bribes to officials and health-care workers in order to increase sales of its products and obtain the necessary permissions from the local regulatory authorities. One expert described the scheme which his pharmaceutical company used, *"schemes used by our company (the ones that have been made public in any case, that is, that I can now tell you about) included the conclusion of fictitious contracts for consulting services, obtaining illegal right to exclusive distribution of products and cash payments. And in this respect we are not alone."* It is profitable for companies to pay bribes, because returns on investment exceed by several times: *"The state machine simply asks you to do this (give bribes), everything is ready for you – pay and take away, so to speak."* Thirdly, because of "over-regulation" in this sphere of the market the number of clinical studies that a drug must pass each year is reduced and a decision-making process based on the results can last up to four years. Clinical studies are also sponsored by companies. This is what a representative from the pharmaceutical company says: *"All the research in Russia are disbursed. (...) The purpose of all clinical studies is to promote the drug in Russia to meet all the requirements artificially created by the state machine. And it is done with the hands of eminent academics, thoroughly corrupt pensioners who are trying to feed their departments and institutions."* According to another expert, in contrast to Europe and America, where there is strict control over transparency and there is less conflict of interest, in Russia, like in other developing countries, *"everything is ready and waiting for your financial support, this practice works without you and you will not enter the market without it."*

In order to promote their products on the Russian market, foreign pharmaceutical companies bribe experts and officials to lobby for them in the Ministry at the federal and regional level as well as among members of the medical community. The scheme can be as follows:

> *"The schemes of cooperation are always different – once they were regular fees for the consulting services, once they were grants to support its non-profit organization, we now have an officially registered agreement about his participation in the so-called pharmaceutical tour or "duh" around the country where its task is to convince local and regional Ministries of Health in collaboration with especially our company, and in the course of lectures to the professional community in the same regions – to persuade doctors to prescribe our products on a piece of paper. It works very well, and this person works simultaneously with a number of pharmaceutical companies and form of cooperation is known to everybody." (Interview, representative of the foreign pharmaceutical company, anonymous)*

The possibility of distributors and representatives of pharmaceutical companies to influence those who directly communicate with customers—doctors and pharmacists—depends on three factors. The first is poor compensation that compels them to become paid advocates of a pharmaceutical company. The second is the

Russian medical community's loss of credibility: *"Doctors are fully discredited as professionals and when a pharmaceutical company appeals to the doctors on this issue, in Russia it does not think of them as physicians. In addition to knowledge, one should possess professional ethics. In this country, doctors usually have neither the first nor the second." (Interview, representative of domestic pharmaceutical company)* The third is the belief of the physicians that foreign products are better, *"the efforts of the same trade representatives of foreign companies form the confidence of our doctors that Russia can not produce anything good. And they do not want to prescribe patients domestic medicines." (ibid.)* Doctors order drugs that they do not necessarily need, but are manufactured by their pharmaceutical patrons, and it is paid for by the state or regional governments, which is an abuse of the public purse. It results in the domination of the public procurement of medicines by certain companies and is anti-competitive and significantly disadvantageous to other companies.

Another important factor which leads to unequal access to medicines is a lack of open and mutually beneficial cooperation between the government and pharmaceutical industry. The experts in our interviews noted that many decisions are made without sufficient understanding of the specifics of the market, and this is largely due to the fact that the negotiations do not occur between all market participants, but between the concerned parties within the Ministry of Health and the pharmaceutical companies that are willing to offer them bribes. Naturally, these transactions often bypass official channels of communication.

Public procurement: HIV patients are left behind

In this chapter we are touching specifically on procurement of expensive life-saving medicines to treat HIV and hepatitis C, a process that has been severely affected by the influence of international pharmaceutical companies playing in the domestic market. Based on our research and analysis of the market, we provide a list of recommendations for the government to eliminate the harmful effects of transnational corporations on public procurement of medicines in Russia, which will facilitate the achievement of the Sustainable Development Goal 3, 'to ensure healthy lives and promote well-being for all at all ages'.

Bidding process and tenders

Public procurement is a complex procedure governed by a number of laws and other regulatory documents, such as Federal Law No. 44-FL "On the Contract System in State and Municipal Procurement of Goods, Works and Services",[xxiii] the Civil Code of the Russian Federation, the Budget Code of the Russian Federation, etc.

Decree No. 2019-p, issued by the Russian government on 31 October 2013,[xxiv] mandates that government bodies purchase drugs via a prescribed public procurement procedure (the so-called 'open electronic auctions'), with a few exemptions mainly related to the auction starting price.[xxv] All the auction documents are available, for free and without requiring an account, online at specially accredited websites.[xxvi] This transparency allows for detailed monitoring by interested parties of government procurement activities; in the field of HIV, research based on this data has been carried out by several stakeholders, including governmental bodies and non-governmental organizations.

Since the government is a very large customer, the auctions are designed to maximize its clout by forcing pharmaceutical companies to bid against each other, thus driving down the prices, which in theory benefits the state and patients. However it also creates opportunities for malfeasance. Companies have colluded to establish minimum bid prices among themselves, including those supplying drugs for treating HIV and coinfections.[xxvii] As stated by representatives of the Federal Anti-Monopoly Service, companies participate dishonestly and can be rightfully accused of anti-competitive practices.

In the pharmaceutical procurement system, corporations play the role of auction participants and are supposed to submit a supporting document package prior to the auction and quote a price during the auction. Only companies holding a license for pharmaceutical activity are allowed to participate in auctions.[xxviii] The offices of multinational manufacturers of HIV drugs conclude contracts with authorized local distributors. Different opinions have been expressed on the subject of whether commercial relationships between manufacturers and distributors lead to anti-competitive practices; representatives of the industry believe the system is transparent, and that perquisites given to distributors in the form of bonuses and discounts should, in theory, lead to price reductions, rather than price increases.[xxix] However, a preferential contract with a certain manufacturer may provide a distributor with significant leverage during negotiations with health-care bodies.

The bid made by the distributor during an auction embraces the manufacturer price and distributor margin, which, as shown in Box 1, can be double the manufacturer's price.

Box 1: Distributors and pharma work in tandem to gain profit

The CCR5 inhibitor maraviroc (brand-named Selzentry) was registered in Russia in 2011. As the drug is not included in the National List of Essential Medicines, its price is not regulated by the government. In 2012, limited volumes of maraviroc were purchased by local antiretroviral therapy programmes, with the starting price based on distributor quotes. The resulting contract price was equivalent to approximately $15,000 per patient per year. At a meeting with civil society organizations, the manufacturer explained that its price offered to the distributor ranged from $7,700 to $8,000 per patient per year.[xxx] In this case, half of the contract amount, which could have been spent on additional medicines, was used for covering the distributor margin.

In Russia, per Federal Law No. 61-FL "On Circulation of Medicines" and Decree No. 865 of October 29 2010,[xxxi] the prices of drugs included in the Essential Medicines List (EML) are subject to government regulation.[xxxii] If the pharmaceutical is on the EML, the price quote should always be limited by the maximum list price; in some cases, distributor mark-ups and a value-added tax of 10 per cent are also applied. Registered prices can be accessed online at a government website, www.grls.rosminzdrav.ru.[xxxiii] The prices are set based on prices from over 20 reference countries,[xxxiv] which include several high-income European and CIS countries; it can be argued that, by choosing high-income countries as reference countries, the government makes it easier for pharmaceutical companies to keep prices inflated. Several experts, including analysts of the Federal Anti-Monopoly Service and non-governmental organizations, have suggested revising the list to include countries which are closer to Russia in terms of the Gross National Income, epidemiology and Life Quality Index.[xxxv]

Box 2:

The price for the combination drug abacavir/lamivudine (brand-named Kivexa) was reduced in 2011 at the instigation of the Ministry of Health, with active support from civil society organizations,[xxxvi] which had pressured the company refusing to participate in the auction at the proposed price. According to the conditions set at auction, the Ministry of Health planned to purchase more pills than in the previous year (over 5700 annual treatment courses as compared with 3520 in 2010), trying to meet the increased demand for antiretroviral treatment. The starting price in 2011 was set at the level of 213 rubles per pill as opposed to 542 rubles per pill in 2010, as reported by Rossiyskaya Gazeta. At first, distributors refused to take part in the auction, allegedly due to the low starting price. In the end, the auction did take place at the lower price set by the Ministry.

As reported by civil society organizations, before this intervention, the price for abacavir/lamivudine in Russia was higher than in the UK.[xxxvii] According to the report "To Treat or Not to Treat" in 2010, the price for abacavir/lamivudine in the government procurement programme in Russia was equivalent to $6597, whereas in the UK at that time the drug was priced at the level of $6429 per patient per year (British National Formulary, 2011).

It is important to note that generic version of drugs on the EML can be registered at a price equal or almost equal to the brand-name drug;[xxxviii] there is no regulatory norm obliging generic companies to register their medicines at a significantly lower price. For instance, the generic version of the drug didanosine (400 mg) produced by Aurobindo was registered at the price of 2244.35 rubles per package; the registered price of the brand product is 2245.35 rubles per package.[xxxix] The chief criticism of setting a 'ceiling' price is that prices tend to cluster around the ceiling. That is, given no particular advantage manufacturers would tend to price near the regulated price ceiling and this could have an adverse impact on competition. Above is the evidence of this phenomenon in public procurement in Russia.

The monitoring that we conducted shows that in several regions of Russia in 2014 some generic drugs were purchased at a price higher than the brand drugs (lamivudine/zidovudine, saquinavir, efavirenz).[xl]

Box 3: Regional discrepancy in prices

As reported by the Treatment Preparedness Coalition in 2014, Tomsk oblast purchased the brand-name drug Saquinavir at the price of 3421.53 rubles per package, while Ivanovskaya oblast purchased the generic version of this drug at the price of 6427.85 rubles per package. Interestingly, the size of the order in Tomsk was lower than in Ivanovo (57 versus 411 packages, respectively).[xli]

Pharmaceutical Industry and Intellectual Property Issues in Russia

According to the current legislation, when formulating the request for proposals, international non-proprietary names should be used instead of trade names.[xlii] There is a government decree stipulating which drug trade names can be used in the requests for proposals. The current version of this decree states that trade names can be used only if a medicine cannot be replaced by the same international non-proprietary name due to the efficacy and safety profile.[xliii] During the public discussions of this list, representatives of the pharmaceutical industry voiced significant concerns over the fact that the final draft did not contain a clause according to which trade names could be used in the auction if the substance is protected by a patent.[xliv] If this clause had been adopted, then competition in some cases would have been limited (for instance, if a generic company finds a way to go round the patent) and brand companies would have had an extra leverage to keep their prices at a high level, limiting access to drugs.

As of January 2015, over 30 international non-proprietary names of HIV medicines are registered in Russia. There are no generic versions available for 17 drugs. Six of the antiretroviral drugs are not on the EML. In order to be purchased within the national treatment programme using the federal funds, antiretroviral drugs must be included in the Decree No. 1438 of December 27 2012 (revisited 1 March 2014).[xlv] As the practice shows, only drugs which are on the EML can be included into this decree.

In certain cases, delayed registration and inclusion of drugs into the EML due to the policy of pharmaceutical companies and the bureaucracy of the Russian regulatory system has kept cheaper and more patient-friendly medicines out of reach and affected the quality of treatment of chronically ill patients in the country.

Box 4: Inequality in access to the new generation of ARV medicines

The antiretroviral drug tenofovir was registered in the USA in 2001; later on, it was included into the WHO guidelines as one of the preferred medicines for therapy initiation. It is still part of the preferred first-line therapy according to the latest WHO guidelines. The drug was not registered in Russia until 2010; Hetero Drugs, India and Gilead released it on the market in 2012, alongside the combination drug Truvada, which contains tenofovir and emtricitabine.[xlvi] In 2015, after a long advocacy campaign, tenofovir (but not Truvada) was finally included into the EML. As a result, for almost 10 years, Russian patients were unable to obtain a frontline medication. The price for generic tenofovir, at auctions held by clinics in Moscow and St. Petersburg in 2012, was close to $3000 per patient per year, whereas the lowest price in the world according to the MSF report at that time was $48.[xlvii]

When setting starting prices at auctions, the health-care authorities, responsible for the procurement, should, first of all, rely on the registered prices (the so-called ‘tariff system’). Another approach to the price-setting process is making a direct request for a sales quote from distributors. As our research has revealed, when customers set prices based on the price of the previously concluded contracts, multinational pharmaceutical corporations tend to ignore the auctions because they are not satisfied with the low initial price.[xlviii] Such self-serving behavior can cause disruptions to the supply of antiretroviral medicines, posing an alarming threat to public and patient health in Russia.

Box 5: Pharma ignores auctions due to lack of incentives to participate

As reported in the report "To Treat or Not to Treat" in 2011 the auction for the pediatric form of the drug nevirapine did not occur because no bids were placed. According to information received, the price of 606 rubles per vial did not entice suppliers who were not eager to enter the auction on these conditions. It is worth noting that in this case the Ministry of Health set the starting price at 606 rubles because this was the closing price at the auction held the year before. At the 2012 auction one bid was received and the contract was closed at a price of 606 rubles per vial.

Even if only one trade name is registered for a particular international non-proprietary name, in theory, competition between distributors is still possible. Although, according to the research carried out by the Treatment Preparedness Coalition, certain manufacturers tend to partner with certain distributors. This tendency is evident in an analysis of 1848 auctions conducted in 2013 in Russia, which found that there was only one distributor participating in 80 per cent of them.[xlix] Thus, there was no actual competition during the auctions, and, consequently, no market forces to drive prices down.

Since 1 January 2013, in accordance with the Government Decree No. 1438 of 27 December 2012, the procurement of antiretroviral medicines is decentralized. The decision meant that each region received funding from the federal level and had to organize competitive tendering procedures on their own. As shown by the monitoring data,[l] decentralization has led, among other things, to the following consequences:

- **Failure of auctions.** Based on the results of the analysis for 2013, 11 per cent of all the auctions analyzed were disrupted due to the absence of bids. The reasons for the companies not willing to participate could be low prices and potentially low margins due to low purchase volumes. As already mentioned above, in some cases companies ignored the auctions, and they had to be re-announced at a higher price. In Ulyanovskaya Oblast, the auction for lopinavir was announced at the price of 6655.49 rubles per package; the auction did not take place due to the absence of bids. Later on, it was re-announced at the price of 6881.77 rubles per package; the total difference in the contract price was over 2m rubles.[li]

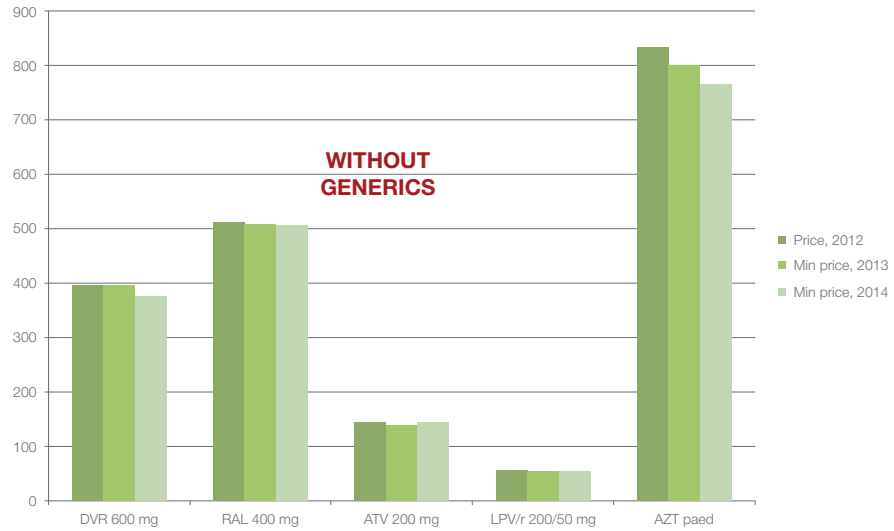
– An **increase in prices as compared to the federal tender prices in 2012.** In 2013 and 2014, many regions purchased antiretroviral medicines at prices significantly higher than the prices of 2012. This has to do with smaller volumes of purchases, regional mark-ups, potential deals with local health-care authorities responsible for procurement and distribution, as well as higher price quotations from distributors. According to an analysis of 2199 auctions in 2013, over 300 million rubles could have been saved if the 2012 prices had been applied to all contracts in the sample.[lii]

Box 6: Detrimental effects of decentralization of procurement

In April 2014, several complaints about a shortage of drugs were received from patients in Murmansk. The issue was widely discussed in the media. The analysis of auctions in Murmansk revealed a significant increase in prices for drugs that do not have generic versions; the price for lopinavir/ritonavir increased by 44 per cent, atazanavir by 32 per cent,[liii] and raltegravir by 50 per cent as compared to prices before decentralization.

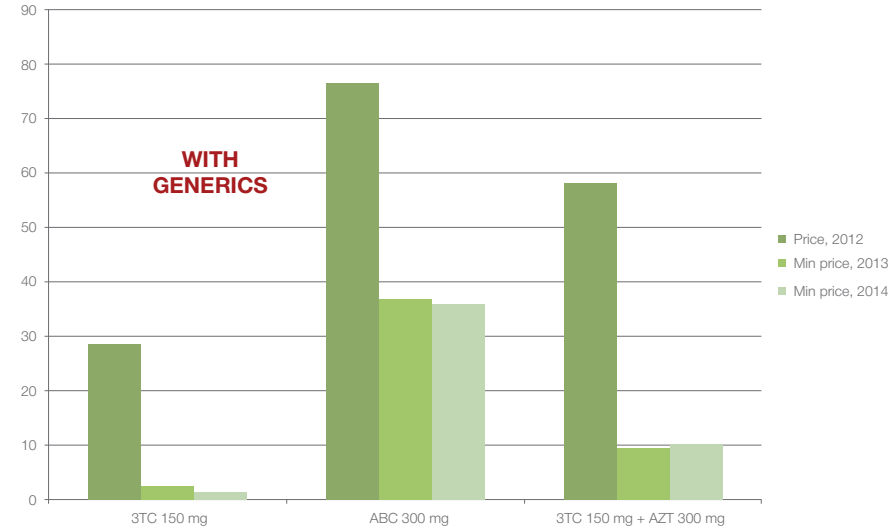
Currently, the federal budget for antiretroviral medicines, according to officials, is not enough to cover all the patients in need of treatment.[liv] Based on estimations of Rospotrebnadzor for 2013, approximately 157,000 patients were enrolled in antiretroviral therapy programmes, while the number of people in need is *nearly double that.*[lv] The number of newly registered patients, many of whom were the so-called 'late presenters' who needed treatment immediately, has been on the rise for many years; yet, given the harsh epidemiological situation, multinational pharmaceutical companies have kept the prices high in the absence of competition. Below follows a brief analysis of the groups of drugs having and not having generic counterparts and the price dynamics for these drugs over three years. Figure 1 (overleaf) shows the price decrease varied from 113 per cent to 1946 per cent for drugs having a generic equivalent, whereas in those without a generic version the price decrease varied between one and nine per cent (Figure 2). This example confirms yet again that **sound generic competition is essential for price reduction and expansion of access to treatment; without competition, pharmaceutical corporations have no incentive to lower prices, unless convinced or forced to do so by the governments.**

Figure 1: Difference in prices for drugs not having generic equivalents



Note: DRV – darunavir; RAL – raltegravir; ATV – atazanavir; LPV/r – lopinavir + ritonavir; AZT paed – zidovudine (paediatric formulation).
Source: Public procurement in Russia, database.

Figure 2: Difference in prices for drugs having generic equivalents



Note: 3TC – lamivudine; ABC – abacavir; AZT– zidovudine.
Source: Public procurement in Russia, database.

Several experts, including the head of the Federal AIDS Service and representatives of the Federal Anti-Monopoly Service, have expressly mentioned the need for pressuring pharmaceutical companies to reduce prices.[lvi] In December 2014, Mr. Kalashnikov, the Head of the Health-care Committee of the State Duma, sent a letter to the Government of Russia, requesting the latter to enable the use of compulsory licenses for HIV and cancer medicines.[lvii] As stated in the document, the need for such a measure is justified by the current economic situation. In the case of HIV, as stated by experts, this measure is also justified by the current epidemiological situation, inequality in access to treatment, and the growing demand for therapy.

Until then, given the current budgetary constraints, health-care managers have been forced to delay initiation of the highly-active antiretroviral therapy, switch to inferior drugs, or use incomplete regimens. As stated by some civil society organizations in Russia, over 150 complaints were lodged in 2014 about limited access to medication.

As policy researchers and members of civil society, we propose the following recommendations:

1. Government agencies should conduct systematic work aimed at reducing prices of originator and generic drugs. The Government should develop and introduce a system of gradual reduction of prices for essential drugs.[lviii] The gradual reduction in prices makes the price of a drug at the end of its patent life relatively low. This system, among other things, should oblige generic producers to sell drugs at a certain level lower than brand drugs (at least 30 per cent).

2. Regular and transparent revision of the Essential Medicines List should be ensured, with the inclusion of a range of stakeholders, such as civil society organizations, patient groups, experts of the WHO, academia; and the centralized online price monitoring system should be in place.

3. The Government of the Russian Federation should issue a decree stipulating the use of compulsory licenses for essential medicines, including those to treat HIV and coinfections, in line with the National Security Strategy, with a focus on second- and third-line treatment;[lix] a special clause should be devoted to the situation when the pharmaceutical company does not make the patented drug accessible, delaying registration of the drug or bringing the drug to the market. More broadly, changes to Russian patent law should be made to provide for stricter patentability criteria such as implemented by India.

4. The Government should revise the current regulatory framework to promote generic competition between producers of essential medicines in line with the Strategy of the Pharmaceutical Industry Development Strategy Until 2020, also ensuring sound quality control of generic drugs.[lx]

5. The Government should take measures to ensure opportunities for faster registration of essential drugs for socially significant diseases.[lxi]

6. The Government should consider the option of returning to the centralized procurement of medicines within the national treatment programme to ensure greater negotiating leverage to fully utilize opportunities for price reduction and budget optimization.

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