

# LOOKING TOWARDS GLOBAL



This is our Communication on Progress in implementing the principles of the United Nations Global Compact and supporting broader UN Goals.

We welcome feedback on its contents.



### Statement of continued support

Dear stakeholders,

I am pleased to confirm that Sopharma AD supports and implements the Ten Principles of the United Nations Global Compact in the field of Human Rights, Labour, Environment and Anti-Corruption. Sopharma AD is already working towards the new 17 Sustainable Development Goals, along with all stakeholders.

In this Report we describe our actions for integration of the Global Compact principles into our business strategy. We also commit to share this information with stakeholders through our corporate communication channels.

Sincerely yours,

Ognian Donev

CEO and Chairman of the Board of Directors SOPHARMA





### **People matter**

Sopharma AD not only respects internationally proclaimed human rights but takes actions through strategic social investment and partnerships.

#### Responsible employer

Sopharma guarantee freedom of association, provide inclusive health and educational services for the employees.

We lead zero tolerance politic to any kind of workplace harassment, abuse or threats. The highly technological process for development and production of Sopharma's medicinal products is licensed according to the GMP. And providing safe and healthy working conditions is part of the standard but extends commitment to ensuring our workers and all employees' work places, according to their knowledge and skills and invests in their development.

Training programs offered to employees of the company, aims increasing their competence levels. The training policy is specifically aimed at providing high professional knowledge and improving awareness related to health and safety issues. Employees are entitled to higher remuneration, required by applicable law for overtime, night shifts and working weekends and during holidays. Employees who work in specific, harmful or dangerous conditions receive personal protective equipment and allowances.

# Responsible corporate citizen

- We believe that transparent and responsible governance is the only way to succeed in business and to empower the society. That way we inform not only shareholders but all our stakeholders about Sopharma's business activities and CSR.
- We invest in our local manufactures to protect the economic livelihood of local communities.
- We support one of the most accessible medicines in our markets to ensure the access to modern treatment, including small packages manufacturing to enable affordable treatment.
- Although Sopharma AD is known for many years with its traditional production of several unique products based on plant extracts obtained by in-house-





developed extraction technologies, we invest in generics, according to the EU politics to develop the healthcare system for affordable treatment, mainly through generics.

- Social disease responsibility We bring a market issue of one of our product to a
  higher level as an affordable way to manage with one of the most serious noncommunicable disease in the world smoking cession.
- We run our social responsibility programs to improve lives and to ensure sustainable development of the society.
- We work in partnership with members of the Global Compact Bulgarian Network, professional communities, local authorities and the government. We strongly believe that partnership towards sustainable development is the way to be responsible corporate citizens.

Activities	2015	2014	Change %	Share in
	BGN '000	BGN '000		expenses %
In company				
employees				
freedom of association	three labor unions, where of two national represented and			
	one "in-house"			
Gender equality	Men 707	Men 684		37%
	Women 1182	Women 1145		63%
Education services				
Trainings	204	136	50%	4%
In-house kindergarten	The kindergarten works at full capacity			
Inclusive health services				
Medical services through	789	744	6%	2%
extra access to health				
care resources				
through free additional				
health insurance +				





annual preventive health					
check-up					
Free dental services in					
Sopharma's dental care					
Sport center including					
free fitness					
In the community					
Investments in local	133 810	94 434	42%	34%	
manufacturing					
Affordable medicines *	Sopharma AD has a 4 % share of the total Bulgarian				
	pharmaceutical market in value and 14 % of sales in				
	volume, compared to 12 % in 2014.				
CSR programs	We start different measurements of return of investments				
	in our social responsibility programs				
Donations	373	191	95%	7%	

# Responsible corporate citizen

#### Responsible business and transparency

Today formula for success expressly includes the human, natural and intellectual capital. This is a revolution. Today we are looking for an evaluation of the company impact which is more fair, correct and comprehensive. Impact on the market and on society regarding their customers, employees, investors, local communities.

#### Sopharma is among the 17 Top Bulgarian companies

Sopharma is among the 17 Bulgarian companies in the Top 500 of the international credit insurer - Coface CEE. The ranking is for the largest companies in Central and Eastern Europe and has been published for the seventh consecutive year. The Bulgarian companies for 2014 are 17 and their total turnover reached 17.99 billion





euros, which is 4.24% growth. The total turnover of all companies included in the ranking is 572 billion euros.

# Ognian Donev: We spend more resources on science and progress, for Banker newspaper

- Mr Donev, your company completed 2014 with profit but both it and its sales are declining. Do you expect this tendency to continue during the coming months?
- The main reason for the lack of growth last year is the crisis in two basic markets where the company has long traditions and very good positions in Russia and in Ukraine. The unpredictability of the situation there caused discrepancy between our plans (for the year) and reality. Since it is not possible to make corrections on the production program and the contractual relationships with our partners in such short terms, the costs levels remained the same, while incomes fell drastically mostly due to the objective loss of the eastern part of Ukraine's market. In addition, the jumps in the exchange rates on both markets resulted in accumulation of serious losses from exchange differences. Despite that, we managed to cope and keep our positions on these markets.
- And do you look for new markets after what happened in Russia and Ukraine?
- Our strategy for expansion, mostly in the region, is long-term and we constantly work in this direction. In the pharmaceutical sector however, we cannot expect things to happen quickly. This is understandable, it is one of the most regulated sectors and each entry on a new market or registration of a new product takes at least a year. We have not stopped to look for suitable investment opportunities in neighboring countries in the form of acquisitions or partnerships, but in the current situation we've become more and more careful with the choice of new ventures.
- Do you plan investments to improve the products you offer?
- The products we already manufacture are with European quality, since all our plants comply with the highest contemporary requirements. Of course, we invest, when possible, in process and technology optimization, and with the completion of the modernization of our production capacities, we now spend more resources and attention on science and progress, including on new products or new forms of already existing products.





## Sopharma was awarded with "Best IR Initiatives" in 'IR NOWADAYS - IN THE **EYE OF THE TIGER?' Conference**



The International Conference "IR NOWADAYS - IN THE EYE OF THE TIGER?" held in our country between 24 and 26 September 2015 and was organized by the Association of Bulgarian Investor Relations Directors (ABIRD) to celebrate its 10th anniversary. Annual IR awards were also established for the first time. Among the major topics of the Conference are: Status, Priorities and Perspectives of the Bulgarian Capital Market; The Impact of Global Capital Flows on Emerging Markets; Why Digital Matters for Investor Relations?; IR Online; Electronic IR Website and the Center of Financial Communication Strategies; The Power of News, etc.

The Conference "IR NOWADAYS – IN THE EYE OF THE TIGER?" was organized with the cooperation of some of the companies most active in investor relations in our country, such as IPREO, Bloomberg, Sopharma, Message, First Financial Brokerage House, Industrial Capital Holding AD, Agria Group Holding JSC, Stara Planina Holding.

Effective dialogue is one of the methods to restore the confidence in Bulgarian companies, according to Pelagia Viyatcheva, Investor Relations Directorate of Sopharma AD. "Professionals in the field of relations with investors have been trained together with the building of the capital market in Bulgaria. There is development in all spheres of our work, but predominantly in those contributing to





the return of trust in Bulgarian companies as a possibility for investments, i.e. the disclosure of information, effective dialogue with all interested parties, conducting of general meetings of shareholders etc. ...Communications only can change the assessment of a company. This is the only way to reveal the inner spirit and success to the public."

# For its accessible and transparent financial information Sopharma AD is a leading example at the I-st university competition for financial analysis of the CFA Association in Bulgaria

A team from the American University is the winner who will represent our country at the finals of CFA Research Challenge in the USA this April. The Bulgarian CFA Association held for the first time in Bulgaria the university competition for financial analyses CFA Research Challenge, reported from the association.

Sopharma AD was selected for a public company subject to the financial analysis, considering the reputation of the company based on its accessible and transparent financial information. The teams prepared a written financial analysis of Sopharma AD under the guidance of competent mentors from financial sector.

#### • Affordable medicine

Sopharma AD has a 4% share of the total Bulgarian pharmaceutical market in value and 14% of sales in volume. (12% for 2014)

\*The positions of the main competitors of the Company in the country are as follows: Novartis – 7% (4% in units), Roche – 6% (0,3% in units), GlaxoSmithKline – 6% (3% in units), Actavis – 4,8% (12% in units), Sanofi-Aventis – 4,3% (3% in units), Astra Zeneca – 3,3% (0,9% in units), Bayer – 2% (1,9% in units).

#### Donev: Sopharma gets less than 2% of the state funds for medicines

for Business Start broadcast on BloombergTVBulgaria

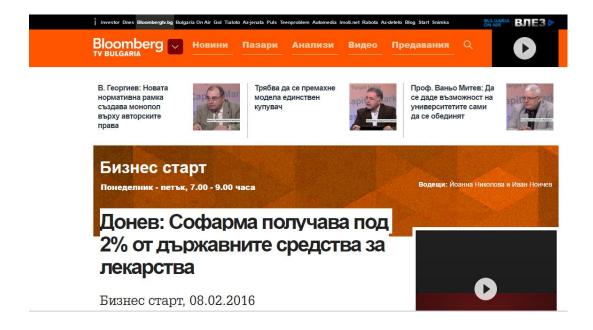
Sopharma gets 1,8% of the public resources spent on medicines. *The Government should take into account that progeneric policy is the one to result in savings.* 

According to his words, although the European practice is for generics to be increasingly penetrating the market, their share in the whole South Europe is very





small. According to him, the use of generic medicines will present a possibility to decrease costs and save means for innovations.



Donev stated that the allegations for the sale of the business are speculations and that expansion by purchases abroad may be expected in 2016. "The slump in sales by 14% last year is as a result of the international situation", commented Donev. However, he stated that the company has achieved good financial results. According to his words, its shares enjoy a good interest both from Bulgaria and from abroad. "Export is the locomotive of economic development of Bulgaria and provides jobs in this country", said Donev. It is important for Sopharma as well, its sales in Bulgaria being barely 30% even in its best years, according to his words.

# The European Generic and Biosimilar Medicines Association adopted the disclosure requirements in its Code of Ethics

On 01.15.2016, the members of the EGA, whose member is the Bulgarian Generic Pharmaceutical Association (BGPharmA, whose member is Sopharma AD) adopted unanimously the disclosure rules. These rules will constitute an important part of the Code of Ethics of EGA (EGA's Code of Conduct), which was adopted a year ago. Without generics medicines, the payers in Europe would have to pay 100 billion euro more in 2014. The share of generic medicines is 56% of all administered medicines,





but only 22% of the pharmaceutical expenditure in Europe. The vision of the European producers of generic and biosimilar medicines is to provide sustainable access to high-quality medicines for all European patients based on five important pillars: patients, quality, value, sustainability and partnership.

# Ensuring health equity and access to quality and effective treatment for patients in Europe and worldwide

At the 21st Annual Conference of the EGA, President Mr Nick Haggar said that there is still a huge opportunity to increase access to medicines through competition in generic medicines across Europe (from 55% to 75% of medicines) to be sustainable and ethical (according to the newly approved Code of Ethical Behaviour of EGA). Over 230 participants from the industry and key partners from the WHO, the European Commission, EMA, OECD, patient organizations, national medical regulatory authorities discussed future challenges, among them methods of supporting active lifestyles and health of the EU population, improving the health systems sustainability and implementing the Directive on Falsified Medicines.

#### Ognian Doney: Pro-generic medicine policy favors society,

for Bulgarian National Radio

According to one of the purposes of the latest healthcare strategy, Bulgaria has to spend more public funds for medical treatment of patients with generic medicines, which are much cheaper than the original drugs. Thus, this country would be able to save a substantial amount of money. Chairman of the Board of Directors of Sopharma pharmaceutical company Ognian Donev told Radio Bulgaria that the authorities have to put more efforts into the country's pro-generic medicine policy:

"We are still waiting to see real policy in this field. The authorities must find a suitable solution, which would be in favor of the Bulgarian patients and reach a balance between the use of innovative and generic medicines. Any pharmaceutical company can produce generic drugs when the patent over a given original product expires. It usually happens 20 years after a given original drug appears on the market. The





Bulgarian Drug Agency ascertains the equivalence between the original and the generic drug. Consumers must be well informed before they make their purchase and be aware that they can pay different prices for the same active substance. If there is a deficit of money in a given system, the authorities should allow people to benefit from cheaper medical treatment. The contradistinction between generic and original medicines has been going on for many decades. Some consumers still believe that the original product is better than the generic one and are not aware that both medicines have the same active substance. We support the use of both products, because some new medical treatments require the use of innovative chemical molecule, which is expensive. That is why the society must make savings, whenever possible. This is where all producers of generic drugs, including our company, can be helpful."

The new health reform envisages the establishment of a centralized electronic system, which is to purchase medical equipment and drugs for the needs of the Bulgarian hospitals. In Ognian Donev's view, this is a very reasonable idea.

"Bulgaria is among the EU countries which levies the full VAT rate of 20% on its drugs. Meanwhile, many sectors of the national economy insist that the authorities must reduce the VAT on their produce. Unfortunately, the local administration does not have enough capacity to use different VAT rates. That is why I do not believe that we will witness different rates in this industry any time soon. If this country adopts different VAT rates, it will have to increase the number of its public administration, which is not a good idea. Tourism is the only sector in Bulgaria, which managed to adopt lower VAT rate, which helps this country accumulate higher volume of foreign currencies. With regard to the healthcare industry, I believe that the country must use most of the public financial resource for the treatment of socially-significant diseases. Foreign countries say that Bulgaria has exotic healthcare fund, i.e. this country spends most of its public resource to treat illnesses which affect a small group of the Bulgarian society. Although it is difficult from an ethical point of view to define which disease is socially-significant and which one is not, the authorities must spend most of the public money on the treatment of cardiovascular illnesses, or ones which affect large groups of the Bulgarian society."





The export of Bulgarian pharmaceutical products to Ukraine and Russia has dwindled a lot over the recent months. In Ognian Donev's view, this was due to the depreciation of the local currencies. As a result, the solvent demand of the population of these countries has fallen. Bulgaria's tourism has been also negatively affected by the depreciation of the Russian Ruble and the Ukrainian Hryvnia. "In that case, the family budget becomes scarce and people are not able to buy expensive imported goods. That is why we should not look for other reasons behind this crisis, such as political relations, etc. As a whole, the companies from the pharmaceutical sector are privileged to some extent, because our produce falls within the category of the first necessity items and if people have to make savings in their family budgets, they will limit the purchases of luxury goods first, postpone travels abroad, etc.

# Ognian Donev: Tenders for specified quantities will reduce the price of the medicines paid by the Health Fund,

for TV talk show "The Day on Air" with Veselin Dremdzhiev



The medicines in Bulgaria are among the most expensive in Europe because of the absence of different VAT with respect to the other goods and services. The dispute with the state is long-lasting but no indications of any change in the tax rate can be expected for the present. This is the comment of Ognian Donev, Executive Director of Sopharma.

This concerns VAT reduction in particular and the manufacture of pharmaceuticals, irrespective of the manufacturer, since for Bulgaria the share we pay from our pockets is larger than the share of European consumers.





The lack of pharmacies in small settlements is a problem that could be solved partially, Donev commented. In settlements of about 50 persons or less neither the state nor the industry have any economic interest and possibility to open a pharmacy. However, there are some places where pharmacies could be opened on geographic and demographic principles, he added.

The dispute of the amount that the Health Fund should pay for life-supporting generic medicines, which are cheaper, instead of the originals, is long-lasting, commented the owner of Sopharma.

The dispute is about the issue that since some innovative therapies are extremely expensive, should this be co-financed by the generic manufacturers who are totally unconcerned. The balance should be found. What is sought is higher burden on generic medicines wherever possible.

Donev proposed the German model as a solution, i.e. the state should launch a tender for a medicine according to the level of its consumption. Then the applicants ready to offer lower prices will be more. Thus the lowest offer will be chosen and the costs for the state will be lower respectively.

Sopharma makes investments in Belarus as well. The company is building new production facilities in the town of Dron. The export of the pharmaceutical enterprise to third countries has not been affected, was Donev's comment on the sanctions to Russia and Iran. Nobody should commit genocide against its own people. We have transactions and we make deliveries to Iran. We are not under embargo. Medicines have never been subject to sanctions.

Donev wished the Health Minister successful completion of the initiated health reform. According to the businessman, it should be performed by the doctors in particular. However, a balance should be found between the reasonable claims of the medical professionals and the use of the system for fund draining.

# Improvement of regulatory generic and biosimilar medicines landscape for 2020 for patient needs

On 28.01.2016, the EGA, held the 15th Regulatory and Scientific Affairs Conference where representatives of 61 regulators from 25 countries made progress in improving the generic and biosimilar regulatory landscape for patient needs.





The 2020 European Medicines Agency /EMA/ Strategy, complemented by the 2020 Strategy Paper of the Coordination Group for Mutual Recognition and Decentralised Procedures will pursue operational excellence in the EU Regulatory Network and engagement in international regulatory platforms which will ultimately deliver greater value to public health. *Promoting high-standard global regulatory convergence, supporting a single development programme for generic and biosimilar medicines and optimising the scope of regulatory processes supported by telematics tools will contribute to better access for better health by 2020.* 

#### Social disease responsibility

#### Affordable treatment for smoking cessation

At the end of 2014 New Zealand scientists found out that the medicinal product Tabex® is the most efficient device for smoking cessation. We make our best to spread the news and to ensure further work on the registration of our product Tabex on new markets, especially where this disease is wide spread, with good outlooks.

# Scientists from around the world: Bulgarian medicinal product is a top news headline in the fight against smoking

Manager magazine

A Bulgarian medicinal product is the most efficient device for smoking cessation. This has been announced by New Zealand scientists as a conclusion from an independent study conducted by them. They carried out a study to compare the effect of the Bulgarian Tabex® - one of the leading products in Sopharma's portfolio, and the nicotine-replacement therapy (CASCAID). The results were published in the prestigious medical journal The New England Journal of Medicine. In their opinion, the Bulgarian product exceeded the other agents for discontinuation of the harmful habit, and what is more, at a significantly lower price and within a shorter period of treatment.

Tabex® has been used as a smoking cessation method for over 50 years in Eastern Europe. It contains cytisine, an alkaloid of the plant Cytisus laburnum, known as





Golden Rain. Tabex® interrupts the vicious circle of cigarette dependence by influencing the desire for smoking and the habits related to the pleasure of a burning cigarette.

The study under the title of "Cytisine against nicotine for smoking cessation" was financed by the New Zealand Institute of Innovations in Health Protection and was the first study worldwide to compare the different kinds of therapy. It included 1310 smokers from New Zealand, half of them being given the Bulgarian product for a period of twenty five days, and the other half were treated with nicotine-replacement therapy (nicotine chewing gum, nicotine patches and nicotine lozenges) in a period of eight weeks. Participants were randomly divided in two branches of the study, with respect to ethnic origin, gender, level of addiction etc.

After the study, the head of the New Zealand research team, Dr. Natalie Walker, summarized that "the Bulgarian medicinal product is an effective means of smoking cessation, which can be used as a first-choice medicine for treatment of nicotine dependence and for lasting smoking cessation". During the treatment, those participants who took Tabex® reported over 150% reduction of symptoms of nicotine abstinence compared to nicotine-replacement therapy.

Results showed that Tabex® had comparably better effect that the nicotine-replacement therapy. One month of non-smoking was reported in 40% of the participants on Tabex® and in 31% in those on nicotine-replacement therapy. The follow-up in two and in six months later showed that the Bulgarian product continued to be more effective and resulted in longer refraining from smoking than the nicotine-replacement therapy.

"Smoking is one of the leading causes of mortality worldwide. Since 70% of the smokers wish to give up cigarettes, but only 2,5% are successful, they need a support in the form of pharmacothepary", commented the Head of the Pulmonary Clinic at the Bulgarian Military Medical Academy, Assoc.Prof. Dr.Kosta Kostov. One of the reasons of the good effect of Tabex® is that during its administration the smokers already stop to get pleasure from the harmful habit and they much more easily and comfortably overcome "the terrible symptoms" of nicotine dependence", he added.





Another world authority in the field of medicine, Prof. Nancy Rigotti of Harvard Medical School stated in a TV interview at the beginning of the year that it is a matter of public health significance Tabex® therapy to become available for as many people as possible. This medicine is not only more effective, but more affordable either, it has been used for decades and has a good safety profile, therefore millions of smokers can benefit from it, points out Prof.Rigotti.

The famous scientist and expert on addictions, Prof. Robert West, is even more impressed by the Bulgarian herbal medication. In his comment for New Scientist Magazine he stated unequivocally that in his opinion Tabex® was the greatest news in the field of smoking cessation. "This is a tablet inexpensive to manufacture, which is affordable even for the poorest smoker and which can save the lives of millions", added West.

#### Dr. Frank Bures: Does Europe have a smoking-cessation secret?

"Cytisine has been available in the former socialist economy countries of eastern Europe since 1964. Made by the Bulgarian drug company Sopharma AD and sold as Tabex, it has never been available to most of the rest of the world. A new study from New Zealand reported in the Dec. 18 New England Journal of Medicine compared the cessation results of cytisine to varenicline."







Tobacco is likely the most addictive chemical we humans encounter (except maybe for Oreo cookies. Yes, someone studied them and found an addictive result). The search continues for aids to help people quit tobacco use.

Nicotine gum, lozenges, patches, (all called nicotine replacement therapy), some drugs first intended for psychiatric disease treatments, counseling, hypnosis, etc. have all been tried. Currently the favorite in the United States is a drug called varenicline — brand-name Chantix.

Varenicline was derived from a drug called cytisine. The plant Cytisus laborinium (Golden Rain acacia) first was used as a smoking substitute during World War II. This led to it being used as a smoking-cessation aid, with the extraction of the chemical cytosine coming later. The drug company Pfizer created different forms of it, called analogs, leading to varenicline's formulation and its fast-track approval by the Federal Drug Administration and introduction in 2006 to the United States.

Cytisine and varenicline both bind to the cell receptors for nicotine, of which there are many. The one they have the most affinity for is nicotinic acetylcholine receptor apha4beta2, the cell receptor that appears to mediate nicotine dependence. They only bind partially to give less kick than nicotine itself, but still decrease cravings.

Cytisine has been available in the former socialist economy countries of eastern Europe since 1964. Made by the Bulgarian drug company Sopharma AD and sold as Tabex, it has never been available to most of the rest of the world. A new study from New Zealand reported in the Dec. 18 New England Journal of Medicine compared the cessation results of cytisine to varenicline.

It pointed out right away that the cost of cytisine was far less than all others. The authors listed 25 days of cytisine cost \$20 to \$30, nicotine replacement therapy for 8 to 10 weeks cost \$112 to \$685 and varenicline cost \$474 to \$501 for 12 weeks.

This was the first study to compare the two drugs directly. The subjects were culled from New Zealand's national smoking quit line. They collected 1,310 people, divided them between the drugs, and used a phone self-reporting system for results and side effects. Any time this format is used, criticisms abound. But the results were still valuable.

The reported percentages of abstinence for cytisine vs. varenicline were 60 percent vs. 46 percent at one week, 40 percent vs. 31 percent at one month, 31 percent vs. 22 percent at two months, and 22 percent vs. 15 percent at six months.

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Of course, more studies are needed for approval in the United States. That is the stumbling block here and in Western Europe. The stumbling block to many people wanting to quit now is the cost of what's available. Cytisine would make it affordable almost everywhere.





Perhaps some highly motivated politico can become the standard bearer for getting it approved on a fast track, especially with 50 years' experience other countries. And maybe not.

As Milton Berle, the comedian, said, "You can a lead man to Congress, but you can't make him think."

#### Washington Post: Pill that quashes tobacco urge found in plain sight

Rick Stewart didn't know about the laburnum trees growing in Bulgaria — and their potential to produce a drug for quitting smoking — back when he was the chief executive of the pharmaceutical company Amarin.

He was too deep inside the drug industry, a place often criticized for its short-sighted focus on profits. He had to fail first. Only then could he spot the opportunity in those yellow-flowering trees.

Now, with the help of the National Institutes of Health, Stewart is trying to introduce the laburnum-derived drug to the U.S. market. The pill works by interrupting tobacco cravings, much like Pfizer's top-selling Chantix, but possibly without that drug's high-profile side effects and at a much lower price. A recent run of positive studies have buoyed the pill's prospects. Today, researchers are excited about what could be the first new treatment for smoking cessation to emerge in years.

"We need this," said David Shurtleff, deputy director of the NIH Center for Complementary and Integrative Health, explaining why his agency is helping to get the drug approved.

But laburnum's promise is not new. It was just overlooked — for decades — highlighting holes in how drugs are traditionally developed.







In 2009, Stewart learned of the laburnum trees.

A co-worker told him about a company in Bulgaria named Sopharma that made a stop-smoking drug called Tabex. The pills contained cytisine, a natural compound found in the tree's seeds. The drug was farmed from massive laburnum orchards in Bulgaria. Cytisine targeted brain receptors to block nicotine cravings. Its power had been recognized since at least the 1940s, when Russian soldiers in World War II, short on tobacco, reportedly turned to smoking the tree's leaves. Some soldiers found they no longer needed cigarettes.

Sopharma began making the Tabex-branded cytisine pills in 1964, but they were available only in Central and Eastern Europe.

Stewart had never heard of the drug. But he was intrigued. He was also wary. Nearly 1 billion people smoke worldwide, according to the World Health Organization. Tobacco is blamed for 5 million deaths a year. A cheap, effective drug to help smokers quit would be huge. He wondered how others could have missed this opportunity.

There are only three treatment options for U.S. smokers looking to quit.

Chantix is the newest, debuting on the market in 2006. At the time, it was the first prescription drug approved for smoking cessation by the U.S. Food and Drug Administration in nearly a decade, since GlaxoSmithKline's antidepressant Zyban. Aside from those two drugs, there also are the nicotine-replacement gums, lozenges and patches. But that's it. The promise of treatments such as nicotine vaccines or other drugs had flamed out. Nothing new has come down the pike.





In 2008, Chantix (sold as Champix overseas) posted \$846 million in worldwide sales. But that blockbuster number dropped 17 percent the next year when the FDA slapped a "black box" warning on Chantix and Zyban because of the risk of suicidal behaviors and other mental-health problems. Facing a wave of damaging publicity, Pfizer went on to settle 2,900 lawsuits for nearly \$300 million. Chantix's reputation is still suffering. Last year, it recorded \$647 million in sales.

The risk of severe side effects alarmed Stewart.

Cytisine and Chantix work in similar ways. In fact, Pfizer chemists closely studied the plant product as they developed their synthetic drug. But Pfizer supercharged its derivative to increase efficacy. Stewart noted that Tabex had amassed a database of 5 million users in Eastern Europe without signs of Chantix-like side effects.

"Why aren't we seeing the suicidality?" he recalls thinking. One study suggested it was because cytisine is less potent. And many researchers today believe the worst side effects attributed to Chantix — such as suicidal thoughts — are unrelated to the drug. (A Pfizer study to be released later this year is expected by many to support this notion.) But stark differences between the two drugs are found in other severe reactions, including abnormal dreams, insomnia and nausea. These are rare for cytisine, but seen in up to 30 percent of Chantix users.

Stewart struck a deal with Sopharma. He wanted to get the drug approved in Western Europe and the United States. Instead of calling it Tabex, the pill would be named Extab. But Stewart still faced a daunting problem with cytisine.

"There's no money in it," said Dr. Taylor Hays, director of the Nicotine Dependence Center at the Mayor Clinic in Rochester, Minn., who would love to see cytisine get a shot here. "And that's what usually motivates people to try bringing it to market. The money is going to drive it."

"It's just frustrating to think that there's something that could be helping people and we're not using it," said Dr. Nancy Rigotti, director of the Tobacco Treatment Unit at Massachusetts General Hospital.

A natural product like cytisine cannot be patented. That makes its market position harder to defend. And getting a drug approved requires millions of dollars. Drug companies say the cost of developing and getting approval for a new drug is \$1 billion. This might explain why some companies have seen blockbuster profits with treatments for rare diseases, such as Genzyme's drug for Goucher disease, which costs \$300,000 a year.

"They're fixated on patent protection and new drugs," Stewart said.





Stewart is banking on two things to turn a profit with Extab. One is the limited cytisine supply. A competitor would need to plant vast orchards of laburnum trees hundreds of thousands of them — and wait four years before the drug-containing seeds could be harvested.

The other thing is that Extab is new to the U.S. market. No one has ever tried to get it approved. So the drug would have five years of U.S. market exclusivity as a novel drug under the 1984 Hatch-Waxman Act. That's less than the typical 20-year window for patented medicines. But it's something.

"It's a really old, novel drug," Stewart says.

Still, he needed help getting the drug through the U.S. regulatory maze. He needed to get lucky. And he did.

British medical authorities offered to pay for and run a clinical trial of cytisine. In 2011, the findings were published in the New England Journal of Medicine, showing cytisine was 3.4 times more likely than placebo to help people quit smoking and stay that way for one year, on par with Chantix.

Then a review by University of Sheffield researchers compared cytisine with Chantix and concluded that while more investigation was needed, "Cytisine is estimated to be both more clinically effective and cost-effective than (Chantix)."

But the real turning point came in December, when another study was published in the New England Journal of Medicine. Researchers with New Zealand's National Institute for Health Innovation found cytisine was superior to the nicotine-replacement gum or patch.

The drug now had two large-scale clinical trials under its belt.

But more work lies ahead.

"I'm either absolutely mad or I guess I really believe in it," Stewart says.

European regulators and the FDA are considering what more they need, Stewart says.

#### The entire world could guit smoking if governments followed these 6 solutions

A new study published in the journal Addiction suggests countries have no excuse for not helping their citizens guit smoking. With tobacco still the leading cause of preventable death worldwide, killing some 5 million people annually, even the poorest countries can do their part. The international team of researchers behind the study offer up six methods that are globally affordable and shown to work.

1.	Healthcare	advice

Cytisine





Cytisine is a cheap plant extract that binds with nicotine receptors to make smoking less satisfying. It also alleviates the withdrawal symptoms that make quitting so hard. Cytisine has been in use under the Bulgarian brand Tabex for decades, but, regretfully, has yet to win over scientists in the Western world. According to the new model, cytisine could help people from all income levels quit smoking at a low cost. When used by people who smoke at least 15 cigarettes a day, cytisine has shown bumps to cessation rates of 6 percentage points.



#### **Ex-smoker® Tabex mobile application is on run**

Take extra care of your health – quit smoking assistance – learn, compete, quit quickly and win.









#### CSR programs

#### Sopharma AD in 2015: social commitment with many aspects

Providing information about health culture, prevention of socially significant diseases, providing care for disadvantaged people, public engagement of employees - these are our priorities in the work for the benefit of society.

The social and health care for the elderly- this is not only medical treatment but care and attention as well. The endless waiting and queues in front of the GP's cabinet, sometimes only to measure the blood pressure, is hard for a pensioner. To provide the feeling of actual care and support, we realize social projects in several pension clubs in Sofia, where we provide measuring of various health parameters such as blood pressure, carbon monoxide in the lungs, the volume of inhaled air, as well as a recommendation for a visit to the general practitioner, if necessary. The psychological support is also present in our prevention program, a specialistpsychologist with many years of practice is taking care of that. The project started in the pension club in Lulin and was supported by the Bulgarian Association of Pensioners (BAP), since it gave the pensioners the opportunity to share and solve actual problems that worsen their health and inner comfort.

Our online and mobile presence with advice on physical and mental health #здрави/zdravi and a positive look at life #силен ден (strong day) and created social commitment and focused the attention on health, as well as gained a lot of friends in social networks. A challenge for us is also the joint project with Darik radio #sopharmabike to promote healthy lifestyle in urban environment. Charity and empathy to a friend in need are combined in the expansion of the sustainable project "Help from a friend" which is now in its fifth year with the voluntary participation of Sopharma employees in the form of charity bazaars.

#### CSR programs related to civil society development

#### MediaMIXX 2015

Traditionally Sopharma AD supports MediaMixx - the unique media festival in Bulgaria. In 2015 it has his 21th edition. As the only platform for media and its role in the society the festival brought together representatives from major Bulgarian media,





journalists, media and PR experts and bloggers. The congress was full of topics and discussions on freedom of speech, the new type of media as well as influence and involvement of the media in all problems of the society. Furthermore, comments were made on the future of the media after the digital revolution and the possibility of gamification of media.

#### **Public Communications Investor**

Sopharma AD was awarded with "Public Communications Investor" by Bulgarian Public Relation Society for its 20 anniversary. The award is for investments in Public communication development and it's an unexpected recognition for sustainable and hard work in the field of media and public communications as the basic for democracy.



#### **CSR** programs related to healthy living

#### Italian Ambassador with Two Trophies from 'Diplomats and Friends'

Italian Ambassador Marco Conticelli won two trophies in the 7th edition of "Diplomats & Friends" tennis tournament that completed today and took place at the tennis courts of the National Tennis Center at Knyaz-Borisova Gradina in Sofia.

Ambassador Conticelli defended his single status from the previous year after outplaying the Ambassador of Denmark, Christian Kønigsfeld in the final in category "Over 50 years". The Italian added to his success the cup for first place in pairs,





where his partner was Svetoslav Stankov (Ministry of Foreign Affairs). Stankov himself finished the tournament with two prizes as well, i.e. as the best single in the category "Under 50 years". Ruth Thompson (World Bank) was the best among the ladies in the final, after outplaying Monika Helling, representative of the German Embassy. Winners were awarded by Katerina Genova, Secretary General of Bulgarian Tennis Federation, and Atanas Mladenov – Director of State Protocol Directorate at the Ministry of Foreign Affairs.

Traditionally, the tournament was organized under the patronage of the Ministry of Foreign Affairs. The initiative of the tournament was given by His Excellency the Ambassador of Italy, Mr. Marco Conticelli, and the President of the Bulgarian Tennis Federation, Mr. Stefan Tsvetkov, and was organized with the assistance of Sopharma. Diplomats from Italy, the Netherlands, Germany, Denmark, Slovakia, the USA, Pakistan and other countries joined the tournament together with representatives of various international organizations and institutions, such as the United Nations and the World Bank.





# The Tournament Sopharma 2015 Gathers the Best Sports Shooters in Bulgaria from the 2nd to the 4th of November

The best Bulgarian sports shooters with pneumatic weapons competed in the first edition of the Sopharma tournament between the 2nd and the 4th of November 2015 at Geo Milev Shooting Rangein Sofia. The competition was organized jointly by the pharmaceutical company and Levski-Sopharma Shooting Club, and besides the top shooters with pistols and rifles in men's and women's category, the competition gave a chance to the talents in boys' and girls' category. Sopharma AD plans for the





tournament to become annual and with a continuing focus on the development of adolescents.

"We want the young talents in this sport in Bulgaria to stand next to many of the current champions and to give the best of them, and later to show their talent and skills abroad", said the representatives of the company that began its partnership with sports shooting in 2010 with the formation of Levski-Sopharma Shooting Club.

On the 2nd of November, the demonstration contest for the media under the slogan "Non-smoking Barrels" took place with the support of Tabex, with the participation of two of the best shooters, Maria Grozdeva and Antoaneta Boneva.

#### Zdravi /Healthy social platform



**Zdravi** (**Healthy**) is social platform, that include a mobile application, blog and facebook society, active not only in all social media but also offline. Zdravi app gives everyday advice for healthy lifestyle and health prevention. It has its group of health-supporters in the social media. After the free mobile application "Zdravi" Sopharma is launching the "Healthy" campaign with a portable Interactive installation designed especially for the project. The campaign is dedicated to promote easy to follow practices for healthy living by measuring health indicators, such as pulse, and





providing easy to implement advice according to the health indicators measured, upon performing the advice, the installation drops the participator a present. The installation can be placed at different places where the people passing could interact with.

Zdravi made offline events during the year for healthy cooking, how to be healthy and beautiful, sport events.

#### Zdravi with tow Award from the PR Priz

On The 9<sup>th</sup> PR Priz, part of traditional PR festival of the Bulgarian Purblic Relation Sociaty, Zdravi was awarded for Online project and for CSR project from business sector.





#### #Zdravi with an Award from the First Digital Oscars in Bulgaria

The first "edition" of the international awards for interactive marketing, IAB Mixx Awards 2015 in Bulgaria, took place yesterday in Cinegrand Movie Theatre. The mobile application of Sopharma Zdravi took the digital Oscar in the category Mobile, and it was the only nominated mobile application among 42 applications for participation in the awards in this category. In the category Social, in which it also participated, #Zdravi was among the three nominated finalists.

IAB Mixx Awards are a standard for achievements in the digital world and they outline the future trends of development. The winners inspire the Internet community and influence the whole digital industry, as well as everyone who has touched to the realization of the presented campaigns. Companies compete in 7 categories: "Direct





Response and Lead Generation", "Branded Content", "Cross Media Integration", "Interactive Video Campaign", "Mobile", "Social", "Brave".







Part of the award is also the free participation of the winners from the Bulgarian edition in the awards of the European and the world edition of the Competition: The IAB MIXX Awards New York and Europe.

#### **CSR** programs in Partnership

# Sopharma Supports 'Get Ready to Succeed' Program of the Bulgarian **Charities Aid Foundation**

Sopharma joined the 10 jubilee edition of the "Get Ready to Succeed" charity program of the Bulgarian Charities Aid Foundation. At a special ceremony on the, 120 young men and women were awarded scholarships. Sopharma's choice to support two future medics is not a random one. Pharmacy and medicine have always been inextricably related and the existence of one of them is nowadays unthinkable without the other one. "Doctor" and "Pharmacist" are among those professions that could not develop without people's trust, and the doctor's profession is one of the few so highly important for society. Together, they restore the most valuable asset in life – health.







Supporting students is an important part of the corporate social responsibility of Sopharma, by providing various internship opportunities, and in this case, scholarships. "Grantors are people who believe in your dreams, in your goals. It is important that they support you, but more importantly, you are a part of a community". These were the words with which Deyana Kostadinova turned to the scholarship holders at the ceremony. She is the Secretary of Social Policies, Youth and Sport of the President of the Republic of Bulgaria, Rosen Plevneliev. The scholarships under "Get Ready to Succeed" program were provided this year with the help of over 1000 individual grantors and 45 companies.

#### National CSR projects related to UNGC Network Bulgaria

Sopharma is engage in projects, which aimed different problems, important to the society, such as the meaning of work as act of creativity (I am Proud of the Work of my Parents Project), ecological problems (The Food way Project), anticorruption (Responsible Choice Project), healthy living. This year (2016) we start action plan to SDG with the support of Rosen Plevneliev, President of Republic of Bulgaria. All these projects are possible with active contribution of our employees.





### Labor

"I want to say that our success is due to the hard work of all employees and I would like to thank them", Ognian Donev, CEO

Sopharma AD does not participate in any form of forced or humiliating labour. We provide to our employees decent work and use of relevant and objective criteria for all employment-related decisions.

Employees	2015	2014	Change %	Share in %	
freedom of association	3 syndicates: 2 national representative and 1 "in house"				
Gender equality	Man 707	Man 684		37%	
	Woman 1182	Woman 1145		63%	
Education					
Higher education	820	850	-5%	43%	
Special education	44	49	-1%	2%	
High school education	994	910	-3%	53%	
Primary school	31	20	1%	2%	
education					
Age					
Up to 30 years of age	209	233	-2%	11%	
31 - 40 years of age	421	432	-1%	23%	
41 - 50 years of age	621	564	-2%	33%	
51 - 60 years of age	541	497	-1%	28%	
Over 60 years of age	97	103		5%	

Current decreased by number of employees is mainly due to the transfer of the team, responsible for the products, produced by Sopharma AD and intended for the free market (OTC products), to Sopharma Trading AD.





#### Sopharma AD provides different non-standard fringe benefits to employees

Now that we require much of our employees, we provide also recreation opportunities – these are 4 holiday centers with preferential conditions for our employees.

We have several favorite fringe benefits. Kindergarten "Simba" is definitely one of them. For Sopharma it is the result of the natural development in the company employee-oriented policy and part of our internal communications. Of course, initially this idea was received with surprise and some internal resistance characteristic of every new undertaking, but today it is a place loved both by children and their parents. The kindergarten ensured greater ease and comfort for parents, and our employees' children go "to work" every morning with mama and papa. At present, the kindergarten is attended by 25 children and there is an outdoor playground for them to play on.

The library is another fringe benefit that has become a favorite place for many of my colleagues and at present there are more than 100 regular readers. In addition to classics, one can find there the newest titles from the book market in our country. The interesting thing is that some of the books were given as a present by the employees themselves. The library has also a computer with Internet access, which the employees can also use.

Among non-standard fringe benefits we can mention the area for sport activities called "Healthy". It was at the idea of its employees that Sopharma made a free fitness club that can be visited by any of my colleagues. Yoga and folk dance classes are also being conducted in the territory of the company.

We provide also free training courses and qualification improvement, additional healthcare insurance, food vouchers.

What we find to be especially valuable is health care: there is a possibility for employees to visit medical specialists free of charge, if need be, as well as annual prophylactic examinations. The company provides "mobile rooms" to medical specialists.

We provide also free dental care for our employees at our own dentist's office.





Last but not least is our catering establishment based on the canteen principle, where various meals, including observance of certain diets /Lent, vegetarian/, are offered.

There is hardly a fringe benefit that can be noted as the most important. What everyone here appreciates is the entire policy aimed at improvement of the corporate life of employees. It is a fact that more and more people are committing themselves to companies they work at. To see this happen, a company should also demonstrate loyalty to its employees and should know how to build a creative and effective work environment.

#### I am Proud of the Work of my Parents Project

The projects breaks the stereotypes professions most wanted by children (a photo model, a fireman, a football player) For the third consecutive year Bulgarian companies, among which Sopharma, open their doors to children of their employees. The idea includes programmes and games specifically developed to show children why the work of their parents is important.



600 Children Take Over Factories, Laboratories and Business Spaces within the Initiative

"I Am Proud of the Work of My Parents" initiative aimed at the revival of labour as a value and it took place for third consecutive year in 21 companies, in 19 cities in the





country. This year, the children will learn about 115 professions from more than 15 sectors of the economy.

The sustainability of the national initiative "I Am Proud of the Work of My Parents" leads to its natural expansion and upgrade. In 2015 it ended with the "Career Fair" open for all parents and adolescents.

Since 2014, there has been an exchange of children between the companies. Thus, they have the opportunity to learn about more and different professions.

## 'I am Proud of my Parents' Work' with Annual HR Awards 2015 prize and PR **Prize 2015**

The collective project "I am Proud of my Parents' Work" carried off the prize at the ceremony of the traditional Annual Human Resources Awards. This award was for HR project for effective and operative interaction between business and education. In the category CSR Project in NGO Sector 'I am Proud of my Parents' Work' was awarded for the third year.











# **Production Process | Green Technologies**

All Sopharma' plants works according to GMP standards, but we move forward and invest in renewable sources of energy, smart buildings, etc. Nevertheless one of the most valuable resource is our employee participation in ecological projects.

#### **Energy-efficiency**

**Energy-saving technologies** 

Low environmental pollution

Renewable sources

**European environmental standards** 

Reduced energy consumption and maintenance costs

Comfortable climate in the building

Improved working condition

**Ecological environment thinking** 







#### We are changing together the city we live in

"Zdravi" innovative eco bicycle parking rack was opened during the close competition of the European Tennis Tournament of NTCveterans. It is the first one of a series of bicycle racks by which "#sopharmabike", a joint project of Sopharma, Drag and Darik was closed. The "Zdravi" bicycle parking rack is designed for 12 bicycles and is placed near the tennis courts in the Borisova Gradina. On the occasion of its opening, the future tennis stars undergoing training at the NTC received a surprising present — eco birdhouses, which they themselves have to assemble and place where they want, and an opportunity to leave their bicycles at a beautiful and safe place. The next bicycle parking rack was placed in front of the National Library St. Cyril and St. Methodius. Our ambition is that more new and beautiful bike racks made of natural materials be installed, which would change our urban environment. Bike racks locations have been determined after voting on Facebook, and our next game will show the place of the new bicycle parking rack and what the inscription on it will be.

#### The Trip with Cause "The Road of Food"



On June 5, 2015 / Friday / for the first time in Bulgaria was held educational reality for teens "The road of food" aimed to learn children through play how to shop and cook wisely and what happens to the food waste. This Trip Cause was organized and conducted by the Bulgarian network of the UN Global Compact on the occasion of **World Environment Day**.





The program started in Sopharma Business Towers in 8.30 hours, and the culinary part of the educational reality took place between 9.00 and 10.00 hours. Children from various schools in Sofia took part in the "ostentatious shopping," followed by catering to "party" under the guidance of head chef. After eating cooked themselves meals, participants followed the path of the garbage, which are "produced" to a factory for the processing of waste and the Bulgarian Food Bank. Throughout the journey, the children had the commitment to share their experience on social networks.

The purpose of the trip Cause "The Road of Food" Participants and their friends to build a responsible consumer behavior, to think critically, to seek alternatives to consume in moderation, since every action leads to change for the entire planet.

Every year on June 5 people around the world celebrate the International Day of the environment. The theme in 2015 "Seven million dreams. One planet. Consume in moderation" focuses on responsible consumption and sustainable lifestyle. For the third year in Bulgaria organizer of the initiative was the Bulgarian network of the UN Global Compact.







# Certificate of Appreciation

Thank you for your participation in

# **WORLD ENVIRONMENT DAY 2015**

You have succeeded in making WED 2015 the biggest celebration yet, by choosing a more sustainable lifestyle. Every action counts. Your contribution will go a long way to both influencing the seven billion others on this planet and creating an exponential positive impact to restore the Earth's natural regenerative capacity.

Welcome to the WED community!











# Responsible business and Transparency

Transparent and responsible business is the only way to succeed and build the sustainable reputation and to empower the society.

In our business strategy there is zero tolerance to any kind of corruption and we expect and require not only ethical behavior but actions to fight corruption from all our stakeholders and business partners We interact with all levels of government and therefore have the right and responsibility to express our corporate citizen position.

Sopharma AD contributes to the public debate for anti-corruption policy and as a company leader together with the UNGC Network Bulgaria we develop and conduct the National project Responsible Choice 2015.



The RESPONSIBLE CHOICE 2015 project start officially on the 3rd of April 2015 Georg Kell, Executive Director of the UN Global Compact, was presented at the event organised by the Bulgarian Global Compact Network (BGCN).

"We believe that by our responsible corporate behavior and standards we follow and implement in our everyday activities, we are changing our common reality. By this initiative we want to remind that we all, by our actions and purchases, as responsible citizens have the power to change manufacturing practices, to govern the "fashion" and accustom ourselves and young people to a culture of anti-consumerism.", said Sasho Donchev, Chairman of the National Steering Committee.

The start of the RESPONSIBLE CHOICE Project of Global Compact Network Bulgaria (GCNB) with the United Nations was reflected in the official website of Global Compact. Its announcement was attended by Mr. Georg Kell, Executive Director of Global Compact, who signed also the annual Memorandum of Understanding with the Bulgarian companies. The leading companies in the initiative include Sopharma AD, Overgas Inc. AD, TechnoLogistica AD, ContourGlobal





Maritsa Iztok 3 AD, Mobiltel AD and University of Finance, Business and Enterpreneurship.

The First module of the Responsible Choice is 'Responsible Consumption' and discussion was held at Sopharma AD as a pilot "edition" of the project.

"Responsible Consumption" is a module aimed at the employees of the companies that joined the project, and through it they can share their vision of what reasonable behavior is and how they can be active consumers. These in-house discussions will help in the writing of Responsible Consumer Guide. The daily choices we make, including as participants in the markets, reflect the level of our civil awareness.

By this project, we wish to place citizens in a more active position to have selfesteem and sense of duty that everything depends on them.

#1имазначение #отговорниятизбор



According to data from the initiative UN Principles for Responsible Investment (UN PRI), by the end of 2014, the companies traded on Sustainability Stock exchange numbered 18000, and the assets managed by UN PRI were 45 trillion US dollars. This shows clearly the meaning of responsible corporate citizenship and





transparency. We believe that attracting a new type of "responsible" investors to our company would orient Bulgarian companies and would encourage end users to support the responsible campaigns through their purchases.

As a public company interest to our shares is the right indicator to all our actions and ethical company behavior.

The Company's shares are included in the indices Dow Jones STOXX EU Enlarged, Total Market Index 0.11% weight, with a weight of 5% in the Erste Bank Bulgaria Basket, the certificate of Raiffeisenbank - Raiffeisen Osteuropa Fonds and the certificate ABN AMRO SOFIX - Open-end-certificate and the new blue-chip index Dow Jones STOXX Balkan 50 Equal Weighted Index.

Sopharma AD is one of the three Bulgarian companies included in an index for Central and Eastern Europe (CEE), which the Warsaw Stock Exchange started to calculate on 30 May 2012. The name of the index is WIG-CEE and it is the third one after WIG-Poland and WIG-Ukraine, which is based on the origin of companies by country. WIG-CEE is calculated based on total return and includes income from dividends and subscription rights.



