

**Non-financial Declaration to the Annual  
Financial Statement of Sopharma AD  
according to the requirements of Articles  
48-52 of the Accountancy Act**

**2017**



**SOPHARMA AD**

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## ***Statement of support***

Dear partners,

Permit us to draw your attention to a report on the policies adopted at „Sopharma” in its capacity of a corporate citizen which demonstrate its active and profoundly responsible attitude to the impact of its activities on society. By taking into close consideration the issues of importance to our stakeholders, „Sopharma” follows the commitments it has made as a business entity targeted at achieving a state of sustainable development and prosperity.

In its activities the company supports and implements the Principles of the UN Global Contract and works to reach the UN Sustainable Development Goals adopted in 2016.

Our Declaration contains a description of the major initiatives directed at the integration of the principles of sustainable development into our day-to-day activities and their economic, social and environmental impacts.

„Sopharma” AD communicates its commitments to the stakeholders via all of the currently available communication channels.

## **I. About the Declaration**

The non-financial declaration process describes the commitments to the environment and society which „Sopharma” AD has recognized and which it realizes in the capacity of a corporate citizen to the benefit of its shareholders and investors, the state and local authorities, consumers, customers and its partners. The company maintains an active dialogue with all of its stakeholders in defining the important topics in an atmosphere of transparency and completeness in transmitting the information on its business activities to the interested parties. With a clear awareness of the impact of our business operations on the socio-economic sphere, the natural environment and the community in general „Sopharma” AD has been able to implement a measurement system focused on the actually established impacts and works towards their ongoing improvement.

The report complies with the reporting requirements provisioned in Art. 48 of the Accountancy Act with a description of the policies adopted by the enterprises regarding their activities in the sphere of environmental protection, the various social issues, issues related to employment policies, anti-corruption, human rights etc. It is based on the Official statements on the company’s progress submitted by „Sopharma” AD as of 2006 - on the active level since 2012 and on the "advanced" level as of the year 2016.

## II. Scope of the Declaration

The presented information provides a broad overview of a number of aspects of Sopharma's activities in its capacity of a corporate citizen. It focuses on the company's initiatives realized between March 2017 and March 2018 and it offers a volume of quantitative data as an instrument for assessing the impacts on the major spheres of interest as described further in the present document

### Sopharma AD

#### *Our core values*

- ***We produce the highest quality generics and our own originals medicine***
- ***We promote the health of our stakeholders through social projects and information***
- ***We practice and advance environmental stewardship***
- ***We serve and support our local and global communities***
- ***We create ongoing win-win partnerships with our suppliers***
- ***We support team member happiness and excellence***
- ***We create wealth through profits and growth***

### 1. Vision, strategy and corporate governance

#### *Vision and strategy*

The vision and strategy pursued by Sopharma AD are determined by the corporate philosophy and the mission which the company has undertaken to follow and which serves as the basis for its activities.

#### *Corporate philosophy*

The production of medicines is not a simple technological process; it is a human mission based on the highest standards of quality, safety and medicinal effectiveness.

#### *Mission*

The mission of the company is to contribute to the progress and development of the pharmaceutical industry and from there to the overall economic development and prosperity of the Bulgarian nation.

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Since its establishment in 1933, the company strives to provide affordable, effective and up-to-date medicines to the Bulgarian patient. Sopharma AD is the successor to the production and pharmaceutical laboratory of the Bulgarian Pharmaceutical Cooperative Society, founded in 1914.

The production of medicines in a wide and modern portfolio, the creation of new jobs, sustainable development and the economic contribution of the company have been the company's leading principles ever since the establishment of the production laboratory and they are the principles to which Sopharma adheres to this today.

Sopharma AD aims to develop, produce and deliver affordable, modern and efficient treatment to millions of patients in Bulgaria and to offer its products on the markets it has been able to access.

The company has formalized its sustainable development activities through its 2004 UNGC accession. Since its establishment it has been actively involved in various regional network projects and - starting in 2016 - has been considered an "advanced entity" as defined in the Official statement on progress. This highly responsible corporate behavior lays at the foundations of Sopharma's business development. The CSR strategy is a part of the company's economic program and the various initiatives and projects support Sopharma's core business activities forming a part of the company's DNA.

Sopharma's vision, mission and values define its activities and the direction of the company developments

### Corporate citizenship policies

Corporate citizenship of Sopharma develops according to following regulations and rules:

Corporate citizenship regulations and rules	Description	Adoption date	Last update
Republic of Bulgaria Constitution		1879	2015
10 principles of UNGC	The Global Compact asks companies to embrace, support and enact, within their sphere of influence, a set of core values divided in four major categories as follows: <i>Human Rights:</i> Principle 1: Businesses should support and respect the protection of internationally proclaimed human rights within their sphere of influence; and Principle 2: make sure that they are not complicit in human	2004	2016 SDG

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SDG	<p>rights abuses.</p> <p><i>Labour Standards:</i></p> <p>Principle 3: Businesses should uphold the freedom of association and the effective recognition of the right to collective bargaining;</p> <p>Principle 4: the elimination of all forms of forced and compulsory labour;</p> <p>Principle 5: the effective abolition of child labour;</p> <p>Principle 6: eliminate discrimination in respect of employment and occupation.</p> <p><i>Environment:</i></p> <p>Principle 7: Businesses should support a precautionary approach to environmental challenges;</p> <p>Principle 8: undertake initiatives to promote greater environmental responsibility;</p> <p>Principle 9: encourage the development and diffusion of environmentally friendly technologies</p> <p><i>Anti-Corruption:</i></p> <p>Principle 10: Businesses should work against all forms of corruption, including extortion and bribery.</p> <ol style="list-style-type: none"> <li>1. End poverty in all its forms everywhere</li> <li>2. End hunger, achieve food security and improved nutrition and promote sustainable agriculture</li> <li>3. Ensure healthy lives and promote well-being for all at all ages</li> <li>4. Ensure inclusive and equitable quality education and promote lifelong learning opportunities for all</li> <li>5. Achieve gender equality and empower all women and girls</li> <li>6. Ensure availability and sustainable management of water and sanitation for all</li> <li>7. Ensure access to affordable, reliable, sustainable and modern energy for all</li> <li>8. Promote sustained, inclusive and sustainable economic growth, full and productive employment and decent work for all</li> <li>9. Build resilient infrastructure, promote inclusive and sustainable industrialization and foster innovation</li> <li>10. Reduce inequality within and among countries</li> <li>11. Make cities and human settlements inclusive, safe, resilient and sustainable</li> <li>12. Ensure sustainable consumption and production patterns</li> <li>13. Take urgent action to combat climate change and its impacts</li> <li>14. Conserve and sustainably use the oceans, seas and marine resources for sustainable development</li> <li>15. Protect, restore and promote sustainable use of terrestrial ecosystems, sustainably manage forests, combat desertification, and halt and reverse land degradation and</li> </ol>	2015
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	<p>halt biodiversity loss</p> <p>16. Promote peaceful and inclusive societies for sustainable development, provide access to justice for all and build effective, accountable and inclusive institutions at all levels</p> <p>17. Strengthen the means of implementation and revitalize the Global Partnership for Sustainable Development</p>	
Code of ethics	Defines the rules of ethic and professional behavior applicable to all activates, preventing bureaucracy, corruption and other illegal practice, aims at increasing public trust in their moral and professionalism and at corporate reputation.	2007

As a corporate citizen, Sopharma AD operates on the basis of the constitutional principles, the laws and regulations of the Republic of Bulgaria and in all its actions respects the regulations of the state, the requirements placed by the local authorities and other regulatory organs. The company closely monitors and abides by the changes in the legislation governing its concrete business activities.

In preparing its development strategies and daily commitments, Sopharma AD follows the 10 principles of the UN Global contract and creates and participates in the programs supporting their implementation not only within the company but also in society as a whole.

### *Sources of corporate governance*

Corporate management systems employed for the management and operation of Sopharma AD:

Corporate governance systems	Description	Adoption date	Last update
Sopharma's Articles of Association	Sopharma's Articles of Association define the corporate purpose, operations on capital and shares, the activities of the corporate bodies and the principles governing their relations.	2003	2015
Decisions taken at the General Meeting of Shareholders	Decisions taken at the General Meeting of Shareholders.	Decisions taken at the General Meeting of Shareholders are updated at least once a year	2018

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Code of conduct of the board of directors of Sopharma AD	Code of conduct of the board of directors of Sopharma AD.	2007	
Good corporate governance program	Good corporate governance program.	2009	
Good Manufacturing Practice GMP	The good manufacturing practices is a system of rules and procedures which serves to guarantee the high quality of the medicinal products at every stage of their manufacture. Its major purpose is to protect the patient's health.	2003	2017
Good distribution practices /GDP	The good distribution practices is a system of rules and procedures which serves to guarantee the high quality of the medicinal products at every stage of their manufacture. The quality and the integrity of medicinal products can be affected by a lack of adequate control.	2003	2017
ICH "Q8 Pharmaceutical Development"	Principles and examples of Pharmaceutical Development.	2004	2017
ICH "Q9 Quality Risk Management. ISO 17025	Principles and examples of tools of quality risk management.	2006	2017
	General requirements for the competence of testing and calibration laboratories.	2014	2017
ISO 13485	Quality management system for medicinal products manufacturing.	2014	2017
AXAPTA	ERP programme, business management of processes of planning, manufacturing, supplies, marketing, financial management and control, management of clients relations, business analyses, etc.	2013	2018

***Detailed description of the corporate management systems:***

- **Decisions made by the General assembly of the shareholders in Sopharma AD**

As a rule, the General assembly of shareholders is convened once a year. It has the power to amend and supplement the Articles of association of the company; to make decisions regarding the capital of Sopharma AD and to approve the annual financial statements - after their



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certification by the appointed auditor - as well as decisions regarding the issuance of bonds, profit distribution, etc.

Extraordinary General assemblies are convened in the event of mergers and acquisitions, such as those undertaken by the company during the last two years.

Traditionally, and over a cup of coffee, Sopharma AD convenes at least one more meeting with its shareholders at which they get the opportunity to meet and discuss various company issues with the executive director - Mr. Ognian Donev, Ph.D. – and the Director of Investor's relations, Pelagia Viyacheva.

- **Procedural rules set for the Board of directors**

These rules ensure the effective organization of the Board's working sessions which are convened at least once every three months and which are engaged with the decision-making process regarding the managerial and operational issues at Sopharma AD. The company's reports and the transactions which engage more than 50% of the company's equity, are subjected to a vote by the GA as well as all other issues falling within the sphere of competence of the GA.

- **The good corporate management program**

This program conforms to the requirements for efficient regulation, to the internationally recognized standards for good corporate management practices and to the Bulgarian national corporate management code.

- **GMP /good manufacturing practices/**

The good manufacturing practices is a system of rules and procedures which serves to guarantee the high quality of the medicinal products at every stage of their manufacture. Its major purpose is to protect the patient's health.

The GMP certificate is a form of guarantee that the products in each finished batch are of uniform quality. Sopharma AD is a manufacturer keeping continuous records of each technological stage; every separate operation is registered in a record of findings which serves as evidence that the worker has executed the working instructions, given in advance, exactly as required. These records are made during the production process and they show whether all of the measures, required as per the procedures and given instructions, are fully met and the quantity and quality of the finished products meet the expectations. Established flaws are also strictly recorded and the incongruities can thus be quickly and easily identified and the defective products withdrawn from the market.

The GMP include both production and working conditions, the qualifications of the production personnel, the practiced sales system and the method of product withdrawal from the respective market.

- **GDP /good distribution practices/**

GDP include an array of tools used in the activities of wholesale distributors, including the prevention of fake medicinal products entering the legitimate supply chains. Their

implementation ensures an efficient control of the distribution chain and the maintenance of the high quality and integrity of the manufactured medicinal products.

The GDP are applicable to any and all activities including the supply, possession, delivery or export of medicinal products /excluding supplies to the end users/.

The system includes staff competence, working conditions and product storage as well as the permanent control of the entire production process up to the final delivery stage.

- **ICH Q8 Pharmaceutical Development**

This standard applies to the overall process of creating new products: from the development stage to their official registration. It also includes risk assessment and the related quality assurance systems as a part of the product's design and relates to the components of the medicinal product in its entirety: the substances used, the excipients, the drug itself, the development of its formula and the process of its creation; the knowledge accumulated during the entire process and the physicochemical and biological properties of the drug; the development of the manufacturing process and the entire volume of gathered information which may be able to exert an impact on the anticipated final result.

- **ICH Q9 Quality Risk Management**

ICH Q9, together with ICH Q8, serves to promote the development of science-based and risk-based approaches to quality control. ICH Q9 Quality Risk Management refers to quality control, creation-related activities, construction facilities, equipment and power capacities, material control and management, the manufacturing processes, laboratory control and testing, packaging, labeling and various other activities.

- **ISO 17025**

This international harmonized standard contains the general requirements related to the competence of the testing and/or calibration laboratories, including sampling. The standard is intended for use by laboratories which set up their own quality control systems for both the administrative and technical activities. The results (protocols, certificates) issued by the accredited laboratories are used by the regulatory organs, the conformity assessment bodies for product certification as well as by the product manufacturers and others.

The possession of this certificate is a part of the risk control process and it guarantees the reliability of the results obtained from the laboratory tests and assessments and - accordingly - the safety and the quality of the manufactured medicinal products.

- **AXAPTA**

This abbreviation relates to the "Corporate Process Management System". It helps improve efficiency, the making of more precise decisions and improving the interconnections with and between the supply chains. It supports the sales and marketing process, the service management, the manufacturing process from the point of view of planning the necessary materials and capacities; the schedules and work flows as well as product configuration

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management and the delivery chains plus the commercial contracts and distribution planning and quality control issues.

The program enhances the project management process: accounting and invoicing, expenditure control, splitting to sub-projects, financial and human resource management.

- **Internal insider regulations**

The Regulations are targeted at preventing the dissemination of insider information, market manipulations, and consequently - bearing the ensuing responsibility.

## **2. Impacts from the company's business**

### ***Economic impact***

<b>Economic and financial data</b>	<b>2017</b>	<b>2016</b>	<b>% change</b>	<b>Stakeholders</b>
Decision taken by General Meeting for payment of dividends	0,10	0,10	-	Sharholders/
Paid Taxes	9645	10709	-9,94	State and local authorities
Taxes paid (profit tax excluded)	6444	7246		
Profit tax paid	3201	3463		
Payments to suppliers	120 731	118062	2,26	Suppliers /including external services/
Payments for wages and social insurance	40678	36273	12,14	Employees

### ***Social Impact***

<b>Economic and financial data</b>	<b>2017</b>	<b>2016</b>	<b>% промяна</b>	<b>Заинтересовани страни</b>

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Plants	10/ 2069	8 / 2076	25/ - 0.33	Employees
Training courses / BGN '000/	218	197	10,6	Employees
Social benefits and payments /BGN '000/	3390	2459	38	Employees
Medical services	792	802	-1	Employees
Donations	372	340	9.4	Local communities
Investments related to pharmacy and healthcare system	7	8	-12.5	All stakeholders
Investments related to development of the business environment	71	40	77	All stakeholders
Investments to healthy lifestyle programs	67	51	31	Society
Investments in public communications	50	68	-26	Society

***Ecologic impact***

<b>Data</b>	<b>2017</b>	<b>2016</b>	<b>%</b>
Cost of raw materials (electricity, topo-energy, fuels, water; without main materials, waste and impairment) BGN 000	17 386	14785	14
Separate waste collection			-2%

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Air emission	0*	0
Water waste	Waste water is treated in WWTP **	
Employees trainings and inclusion in environmental protection activities	Instruction of employees Instructions for recovery and separate collection of waste Instructions on how to deal with waste substances in the units	

\* Sopharma plants are GMP certified, which also controls the degree of environmental pollution. Emissions of waste gases are below 50 tonnes per year, which according to standards tends to 0. At the same time, the use of water film is a prerequisite for not releasing gases into the atmosphere.

\*\* Organic fillers for tablets have not been used in manufacturing for years, ensuring zero wastewater pollution.

## Employees

Равни възможности за работа по пол, възраст и образование

<b>Employees</b>	<b>2017</b>	<b>%</b>	<b>2016</b>	<b>%</b>
Women	1291	62	1138	62
Men	778	38	696	38

<b>Employees</b>	<b>Total</b>		<b>Relative share%</b>	<b>Women</b>			<b>Man</b>		
	<b>2017</b>	<b>2016</b>		<b>2017</b>	<b>2016</b>	<b>%</b>	<b>2017</b>	<b>2016</b>	<b>%</b>
<b>Age</b>									
30y.	210	189	11,11	181	110	64.54	29	79	-63.3
31- 40y.	435	390	11,54	280	247	13.36	155	110	40.9
41 – 50y.	662	617	7,29	452	416	08.65	210	201	4.48
51 – 60y.	628	530	18,49	383	328	16.77	245	202	21.3
Over 60y.	134	108	24,07	45	37	21.62	89	71	25.4

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<b>Employees</b>			<b>Change in %</b>
<b>education</b>	<b>2017</b>	<b>2016</b>	<b>2017</b>
Higher education	893	799	11.76
Colleges	46	41	12.2
Secondary school	1099	965	13.9
Elementary education	31	29	6.9

**Равни възможности за кариерно развитие**

<b>employees</b>		<b>Women</b>			<b>Man</b>		
<b>hierarchy</b>		<b>2017</b>	<b>2016</b>	<b>%</b>	<b>2017</b>	<b>2016</b>	<b>%</b>
Top management	4	1	1	-	3	3	-
Senior Management	39	17	12	41.66	22	21	4.76
Management	148	81	66	22.73	67	60	11.66
Experts	787	511	449	13.80	276	250	10.4
Nonexperts	1095	682	611	11.62	413	365	13.15

**Право на сдружаване**

<b>Trade unions / number of employees</b>	<b>2017</b>	<b>2016</b>	<b>%</b>
3 2 nationally represented 1 inhouse represented	425	428	-0.70

### 3. Organizational structure

## Corporate Governance system

The Board of Directors, in accordance with the guidelines of the Bulgarian Code for Corporate Governance and the internationally acknowledged principles for good corporate governance, appointed the following corporate bodies to support its activities:

Chairman of the Board of Directors and Executive Management			
Deputy-chairman of the Board of Directors	Member of the Board of Directors	Independent Member of the Board of Directors	Independent Member of the Board of Directors
Director "Business operations, Strategic and Organizational development"	Director "Marketing"	Head of "Quality Assurance"	Representative office of Sopharma AD in: <ul style="list-style-type: none"> <li>→ Ukraine</li> <li>→ Poland</li> <li>→ Kazakhstan</li> <li>→ Baltic states and Belarus</li> <li>→ Turkey</li> <li>→ Azerbaidjan</li> <li>→ Georgia</li> <li>→ Armenia</li> <li>→ Tunisia</li> <li>→ China</li> <li>→ Israel and Palestinian territories</li> </ul>
Chief "Financial Officer"	Director "Security"	Division "Regulatory Affairs - Bulgaria and third markets"	
Deputy Chief "Financial Officer"	Director "Technical matters"	Division "Medical Affairs and Clinical Trials"	
Director "Investor Relations"	Director "Production matters"	Division "European Regulations"	
Director "Institutional Relations"	Director "Coordination of production"	Division "Pharmaceutical Products Safety"	
Director "Intellectual property"	Chief of Production department	Human Resources	
Director "Advertising and Corporate Communications"	Director "Quality Management"	Chief Accountant	

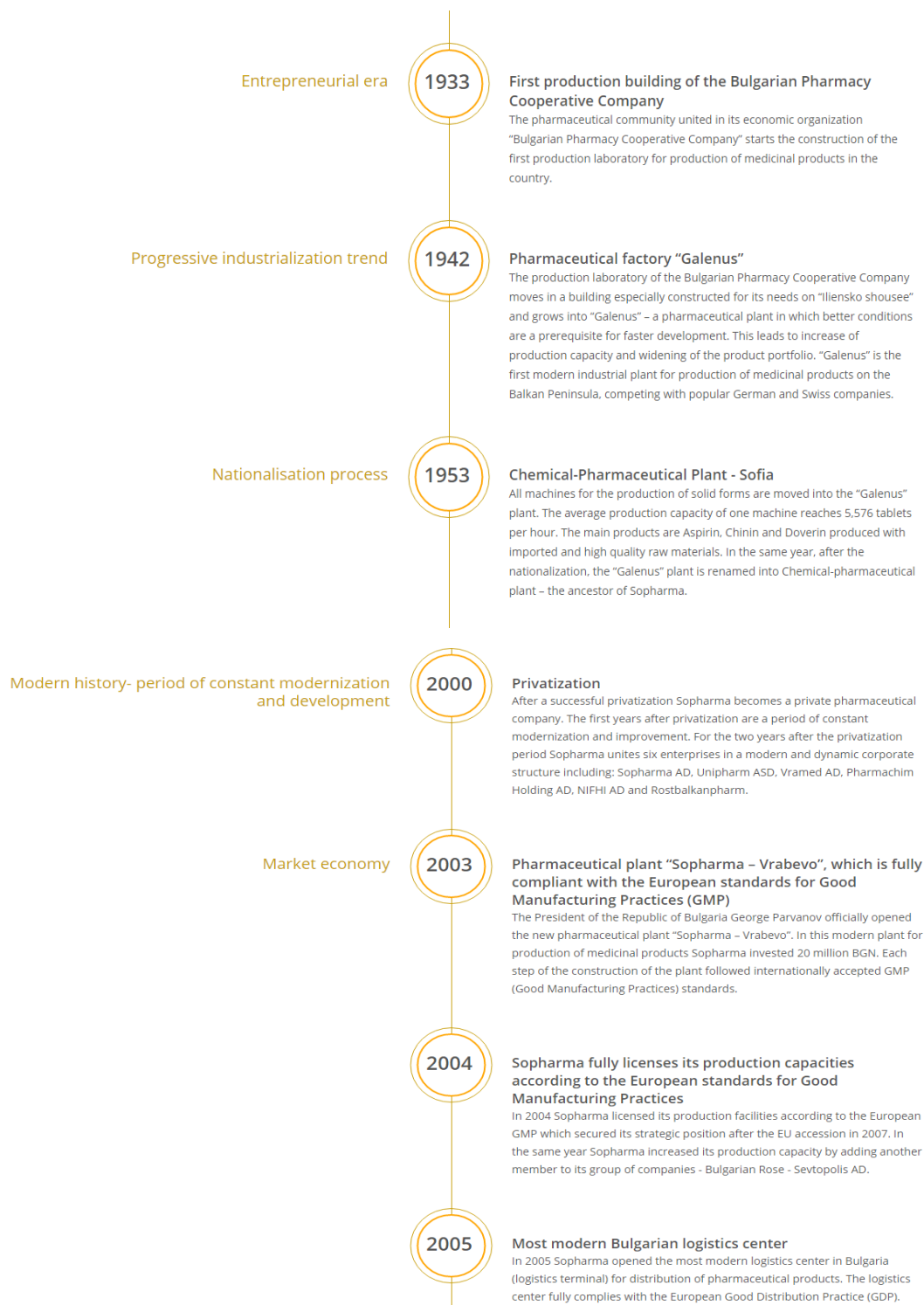
### 4. Products and services

The company manufactures and trades in medicinal substances and forms developing - at the same time - scientific research and engineering activities in the sphere of photochemistry, chemistry and pharmacy. Sopharma AD has 10 production facilities in Bulgaria generating a range of pharmaceutical forms and substances.

The company's activities and production processes are in full conformity with the related national and European legislation, the Good Manufacturing and Laboratory Practices and requirements. In addition to the standards required of the manufacturers of pharmaceutical products, „Sopharma” has also standardized its ISO-related activity through risk management programs and corporate management systems.

### 5. Company development

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### Distribution market

2006

#### Construction of a new high-tech tablet factory for production of solid forms

Sopharma initiated the planning and construction process of a new highly technological tablet factory for the production of solid forms with doubled capacity and investment potential of over 40 million EUR. All activities related to planning, construction and validation fully comply with the European standards for pharmaceutical production and are approved by the Bulgarian Health Agency. For this project Sopharma received the First Class Investor Award.

2007

#### Completion of a new ampoule plant in Sofia

In 2007 Sopharma made the next step in modernization and increased production capacity in the tablet production of Bulgarian Rose - Sevtopolis AD, Kazanlak.

2008

#### The official opening of the new plant for pharmaceutical substances took place in 2008.

Being the only producer of ampoules in Bulgaria in 2007 Sopharma undertook a reconstruction of its ampoule facility in order to increase its production capacity.

2010

#### Registration of the first original product of Sopharma in Western Europe.

Start of construction of two new production plants in Serbia and Bulgaria and establishing of a subsidiary in Poland.

2011

#### The next step in being an excellent public company

Listing on Warsaw Stock Exchange

2012

#### Opening our new administrative offices

For the first time in the modern history of the company we open a new administrative office, more accessible to our guests and partners. For a third consecutive year Sopharma is given the "Best public company" award from the Capital Top 100 ranking.

2013

#### Opening the new state-of-the-art solid dosage forms factory.

The new state-of-the-art solid-forms factory of Sopharma is operational and won three awards in the construction sector. The company takes several steps towards the consolidation of the Group.

2014

#### Opening a new page

After concluding the largest projects for modernization of the production facilities we can now put strong focus on R&D

2015

#### Consolidation and expansion

Bulgarian Rose - Sevtopolis AD is finally merged into Sopharma. Sopharma Trading AD entered the Serbian Market.

### III. Strategy for corporate social responsibility

#### 1. Definition

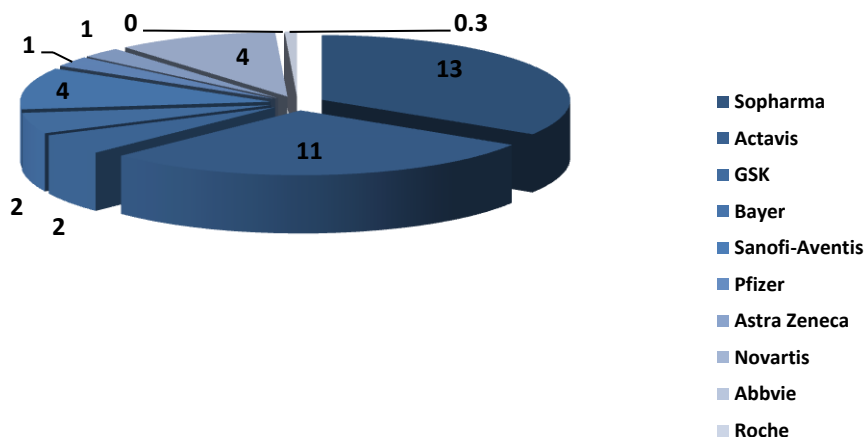
Responsible Corporate Citizenship is, for Sopharma, the only path to a sustainable business development with a clear vision of the goals, the necessary resources to achieve these goals and the impact from the company's business on the economic, social and environmental sphere. Along with the investments made in its business, Sopharma AD is hard at work to achieve UN's SDG by 2016.

Sopharma AD actively shares the information on its activities with all stakeholders. The CSR is a part of the responsible Sopharma AD corporate citizenship. The CSR strategy, initiatives and specific activities are planned and developed, coordinated and implemented by the Communication strategies and the CSR directorate after obtaining the approval of the CEO of Sopharma AD. The Director of the Communication strategies and the CSR directorate is directly subordinated to the Executive Director of the company; the directorate itself is run by a CSR and Corporate communications manager.

*The policies and specific projects are targeted at four major directions:*

#### Market

A responsible behavior towards stakeholders is the only way to do business and to achieve prosperity. The products and business models we create have positioned Sopharma AD among the top 10 companies on the Bulgarian pharmaceutical market and number one in sales /in natural terms/ with a 13% market share.



## Stakeholders

From the point of view of Sopharma AD, an interested party may be any group which is directly or indirectly related to the company's activities; on the one hand this may be any party which has the potential to exert an influence on the decision making process regarding the company's business development as a socially responsible organization. On the other hand, this may be any group on which Sopharma AD exerts its influence on the manner of performance of that group's activities.


The relationship with its stakeholders is the true indicator of the company's success rate; of Sopharma's place in the economic and social life of the country and an assessment of the viability of the adopted course for its development.




- For us, key stakeholders are the patients for whom Sopharma's products are a remedy and the means of improving the quality of their lives.
- Shareholders: being a public company Sopharma AD is responsible before the investors, who have put their trust in the adopted development strategy and the presented results, for each and every decision made. That is why the CSR programs of the company are presented as a part of each annual report prepared and submitted by the management of Sopharma AD.
- The state and local government authorities.
- Partners: Sopharma's success depends on the success of the companies down the chain of suppliers and partner companies.
- Employees: Today's employees are among the most valuable assets of any company, especially in high-tech manufacturing - such as pharmaceuticals - and the investments in personnel generate a considerable return. Employees are the first ambassadors of the company's mission, of its corporate culture and reputation. In addition to the healthy

and safe work environment, career opportunities and the social benefits which Sopharma accepts to be the minimum in its labor relations, the company strives to build an atmosphere of shared common values with its employees and to engage in public projects which are of importance to their own selves.

- Local community: Sopharma AD owns 10 factories in the country and being a major investor in some regions has undertaken responsibilities far beyond its business commitments. The company invests resources in projects of considerable importance for these regions. At the same time - and as the biggest Bulgarian pharmaceutical manufacturer
- Sopharma AD has been able to successfully launch a number of various nationwide campaigns.

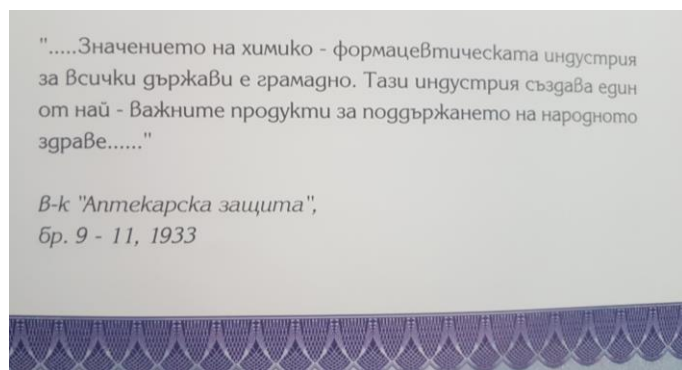
 **Environment** Sopharma works entirely on the basis of the prescriptions of the GMP and GDP standards, but it also invests in creating "smart" buildings, renewable energy sources, the growing of its own crops and so on, the major objective being to reduce the company's negative impacts on the natural environment..

 **Society** Sopharma AD uses its extensive expertise and resources to contribute not only to the economic and social development, but also to enhance the cultural environment and the quality of human life through the creation and development of concrete projects. The company supports the development of an active civil society in the country and takes categorical positions on a number of socially important issues.

## **2. CSR management (corporate social responsibility)**

Corporate responsibility lies at the very foundations and beginnings of the company the major goal of which was to build an industry in support of people's health, to create a livelihood for the population and to further develop the country's economic policy. These far reaching targets are evidenced and clearly revealed in a 1933 publication by the newspaper "Aptekarska zashtita" (The Pharmacist's Guardian, Bul.): „The importance of the chemical-pharmaceutical industry to all countries is enormous. This industry creates one of the most important products for the maintenance of public health“

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From the organizational viewpoint, the CSR was defined as an activity in 2003. It was then a part of the Marketing and advertising department commitments and as of 2013 has become a major priority in the work of the Advertising and corporate communications directorate, headed by a CSR manager. By focusing on socially oriented projects, as a tool for boosting the reputation of the company, this unit is named the "Communication strategies and CSR" department and its is actively engaged in working both with the marketing structures and with the "Investor relations" directorate.

### Core areas of corporate responsibility

#### Strategic Management

Market	Employees	Environment	Community	Corporate Citizenship
Transparent corporate governance	Responsible employer: Zero discrimination regarding the right to work, sex, etc,	Environmental management systems	Contribution to economic development	Anticorruption
Guaranteed product quality and safety	Ensuring the right of association	Reducing the environmental impacts	Developing the healthcare system	Work on SDG 2016
Sustainability	Employee development	Responsible use of resources	Health prevention	Participation in the establishment and implementation of international pharmaceutical




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				standards
Ethical Competition	Decent labor wages	Reduction of direct impacts	Providing Affordable healthcare	Working with partner organizations
Responsible marketing	Ensuring healthy and safe work conditions	Reduction of indirect impacts	Investing in education	Joint projects of organizations in which „Sopharma” is a member
Responsible procurement	Social benefits for employees	Participation in environmental projects	Investments in public communications	Development of the generic industry in the country
Development of pharmacy sphere	Internal communication	Training of employees for separate collection of waste and environmental issues		

### 3. Memberships

In order to adequately create and implement its CSR strategy, Sopharma AD works with partner organizations such as the BKAUSE foundation, the Bulgarian Public relations association, the European association of communication directors, the Investor Relations association. The company is a member of a number of business and branch organizations with which it holds discussions and works on the objectives and challenges faced by CSR in Bulgaria.

**Sopharma is:**

-  A member of the Confederation of the Employers and Industrialists in Bulgaria (KRIB). <http://ceibg.bg/>
-  Member-cofounder of the Association of Bulgarian Exporters (ABE), with goal is to develop the National strategy for export Member of AHK, a connecting link between Bulgarian and German economics, with more than 450 German, Bulgarian and multinational companies – members. <http://bulgarien.ahk.de/bg/>
-  Full member of the American Chamber of Commerce in Bulgaria. The American Chamber of Commerce in Bulgaria unites more than 300 American, Bulgarian and international companies operating in the country from all sectors of economy. All

members of the AmCham share a common vision of corporate social responsibility and a good corporate reputation is one of the most important criteria for membership. [www.amcham.bg](http://www.amcham.bg)

- Member of European Generic Association (EGA), an official representative organization of the European generic industry. <http://www.egagenerics.com>.

- A founder-member of the Association of Bulgarian Pharmaceutical Manufacturers, at present Bulgarian Generic Pharmaceutical Association (BGPharmA), its priorities being harmonization of interests with regard to the general national and international mechanisms for regulation of drug manufacture and use, improvement of GMP principles application and observation of loyal competition principles. <http://www.bgpharma.bg>

- Member of the European organization of manufacturers of medicines sold over the counter, the so called OTC products – the Association of the European Self-Medication Industry (AESGP). <http://www.aesgp.be>

- Founder-member of the Bulgarian National Committee of the International Chamber of Commerce and elected as a full member of the International Chamber of Commerce (ICC). ICC is the most prestigious organization in the field of international trade and international economic relations. Its principal mission is to stimulate transborder trade and investments and to assist business corporations to face the challenges and possibilities resulting from globalization. <http://www.icc-bulgaria.bg> [www.iccwbo.org](http://www.iccwbo.org)

- Member-cofounder of the Association of Bulgarian Exporters (ABE), which goal is to develop the National strategy for export

- Member of Global Compact Bulgarian Network <http://www.unglobalcompact.bg>

- As an active member of BMGD, Sopharma is working towards the achievement of the UN sustainable development goals adopted in 2015. For Bulgaria, they are specified in the Strategic Plan of the 2015+ Network, developed by the member companies themselves.

#### **4. Commitment to stakeholders**

Sopharma AD maintains an ongoing open dialogue with all stakeholders through different communication channels depending on the target group: the official corporate media, official BSE announcements, the social networks.

The dialogue with the shareholders, the central and local authorities, business partners and the non-governmental organizations is carried out both through the traditional communication channels but also via the participation in and the support of a number of various events, discussions and joint projects. Traditional communication channels have been the Sopharma AD corporate site, the Sopharma Group website, the company's activity reports, the progress report submitted to the organs of the United Nations as well as the newsletters published by

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the partner organizations. The informal communication channels include the Sopharma profiles in various social networks, the company's mobile applications, etc.

Sopharma communicates to all stakeholders through different channels:

Stakeholders	Communication channels	Frequency of communication
Patients	Product websites Official corporate sites Corporate website <a href="http://www.sopharma.bg">www.sopharma.bg</a> Website of the group <a href="http://www.sopharmagroup.com">www.sopharmagroup.com</a> FB, Integra, twitter Social platform Zdravi Mobile app Zdravi Mobile app Ex Smoker Market research	weekly when there is new information; Sopharma use its corporate site for news related with European generic association, changes in regulations and laws; etc. daily daily daily daily when needed
Shareholders	Общо събрание на акционерите Уведомления Meetings Official corporate sites	Yearly at least
State and Local authorities	Annual conference "Business meet the Government"  Pharmacy forums  State and Local authorities websites  Official corporate sites  Working groups related to pharmacy and healthcare system	Yearly  2-3 summits per year  daily  daily  regularly
Suppliers	meetings mailing	regularly
employees	Intranet FB	When needed Daily



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	Corporate websites Mailing	When needed
Society	Healthy life conferences Public communication conferences FB, Twitter, Instagram	Daily 4 conferences Daily
Partners	Meetings and conferences  Working groups	Regularly

## IV. Spheres covered by the non-financial declaration

### 1. Market

Sopharma AD (JSC) is aware of its role of a significant factor in the pharmaceutical sector at a European level and in the Bulgarian economy. 12 000 highly qualified professionals are employed in the pharmacy sector in Bulgaria and since the middle of the 20<sup>th</sup> century Bulgaria has marked up growth of the pharmaceutical sector and the market for medicines has increased by 9.5% in value terms and 3.6% volumes for 2016.

As a leading vertically integrated Bulgarian manufacturer, exporter and distributor of pharmaceutical products, the Company imposes standards to the companies along the chain following the principles of transparency and responsibility of the management.

The corporate sustainable development of the Company requires investments also in the spheres of science and development, quality management, industrial property, publicity and transparency.

### Review of the results

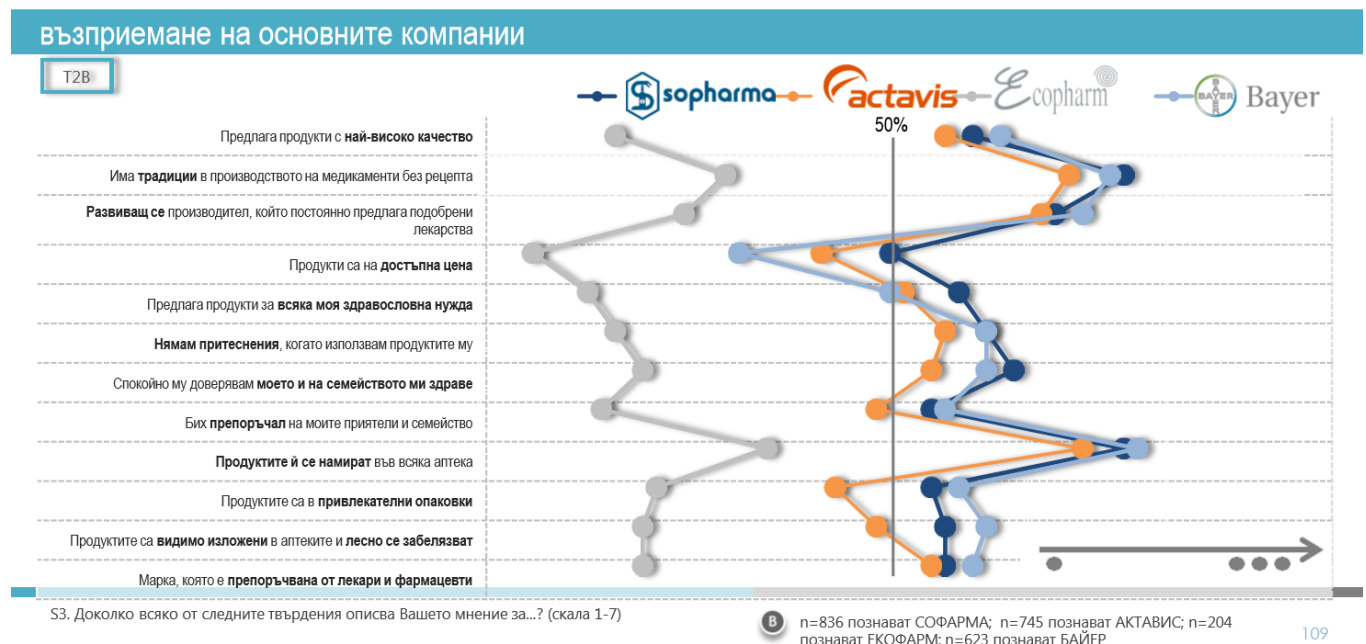
Key indicator	Unit	2017	2016	% change
Revenues from sales	BGN '000	205 259	182 396	12,5
Profit prior to interests, taxes and depreciation	BGN '000	57 309	43 849	30,7%

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<b>Market share in natural terms</b>	<b>%</b>	13	14	-1%
<b>Market share as % of the volume in value</b>	<b>%</b>	4	4	-

Sopharma AD is amongst the companies, along with Actavis and Bayer enjoying the greatest confidence on the part of the users, in conformity with a research conducted in 2017.

СОФАРМА се представя по-добре от основния си конкурент АКТАВИС. БАЙЕР по част от атрибутите изпреварва СОФАРМА. Включително по опаковки и видимост на продуктите в аптеката. Предимствата на СОФАРМА са традиция (почти наравно с БАЙЕР), достъпни цени и доверие.



The market share in natural terms of the products of Sopharma AD as well as the share of the products over the counter are an indicator for the positioning of the Company in the consciousness of the users. The reputation of the Company as a function of the sustainable business model, the quality and the accessibility of the medicines as well as the adequate CSR (Corporate Social Responsibility) Strategy exert also impact over the selection of the end user at the purchase of medicines.

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Sopharma AD is a Bulgarian joint-stock company with a one-tier management system. The Company is managed by a Board of Directors in a membership consisting of: Doctor of Science, Economics Ognyan Donev – Chairman and members Vesela Stoeva, Ognyan Palaveev, Aleksandar Chaushev, Andrey Breshkov. The Board of Directors elects an Executive Director amongst its members who represents and manages the Company: Doctor of Science, Economics Ognyan Donev.

The Board of Directors determines the guidelines and the strategic plan for development of the Company and the operational implementation is performed by a managerial team reporting its activities before the Executive Director Ognyan Donev, Doctor of Science, Economics.

### Production activity

Sopharma AD has 10 production plants in Bulgaria, which function with regard to the requirements of the EU and of the Bulgarian legislation:.

Plant for solid dosage forms, city of Sofia

Plant for solid dosage forms, Vrabovo

Plant for solid dosage forms, Kazanlak

Unipharm

Ampoule plant, city of Sofia

Lyophilic production, city of Sofia

Chemical plant, city of Sofia

Suppository plant

Gamma sterilization

Plant for medical consumables, town of Sandanski

Sopharma AD is the biggest Bulgarian manufacturer of ampoules and suppositories and a sole manufacturer of lyophilic dosage forms in Bulgaria. The construction of a new plant for lyophilic medicinal products is forthcoming.

The production activity develops in the directions:

Substances and preparations on the basis of plant raw materials (phytochemical production);

Ready-made dosage forms, inclusive of: solid tablets, coated tablets, film-coated tablets, capsules;

Galenical - suppositories, drops, syrups, ointments, gels, creams;

Parenteral – injection solutions, lyophilic powders for injections;

Solutions for hemodialysis

Medical articles and cosmetic products, inclusive of patches, dressing products, sanitary-hygienic products; curative cosmetics.

### Products

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Sopharma produces products for the following therapeutic groups: cardiovascular, gastroenterological, dermatological, psycho-neurological, antiallergic, respiratory, analgesic, rheumatological.

The Company has over 210 products in its portfolio, mainly generics  
15 original products, of which 12 on a plant-based basis.

Taking into consideration the responsibility related to its market position, Sopharma invests in new production capacities, technologies and products for the attainment of more accessible and efficient treatment:

<b>Инвестиции</b>	<b>2017</b>	<b>2016</b>
Marketing authorizations / number	3	3
Investments in new products / number	7	3
Pharmaceutical developments of medicinal products and active substances / number	5	10
Investments in new technologies / transferred and validated / number	30	15
Renewal of the production capacities:		
Buildings,	1, 224	1 587
machines, equipment,	4,694	600
new tablet production	6,960	7 429
new ampoule production	5,154	5 457
biological assets	139	134

The Company invests in enrichment of the generic portfolio working for introduction of generic products:

- ✚ Proven efficient
- ✚ Ratified as a golden standard in the treatment of various diseases
- ✚ Topical with regard to the markets

Forthcoming investments in 2018 in:

- ✚ New lyophilic plant in Sofia
- ✚ Building up an extraction capacity in the plant in Kazanlak for efficient production of phyto-products

### **Responsible marketing**

Sopharma AD pursues a flexible marketing policy, taking into account the possible increase of the delivery prices of the raw materials and the materials, the changes in the requirements to the manufacturers of medicines for the suppliers of raw materials, as well as the specifics of the market of medicines. To guarantee the required quality of the substances for its original products (Tabex, Nivalin) Sopharma AD made perennial plants of yellow acacia and grows a marsh snowdrop in its own greenhouse in Sopharma Kazanlak. The value of the biological assets for 2017 was in the amount of BGN 139 thousand (31.12.2016 : BGN 134 thousand).

Sopharma has a developed policy and procedures for evaluation of its counteragents making a regular risk assessment. The Company has over 70 Bulgarian and foreign licensed traders of medicines, with proven history of the interrelations on the main markets as its partners.

The communication messages of the Company are in conformity with the national ethical rules for advertisement and commercial communication.

### **Ethical competition**

Sopharma AD strictly observes the national and European legislation and the requirements related to the rules for competition. The Company is guided in its activity by the conviction that ethical behavior is a mandatory condition for development of the free market. The Company is exposed to strong competition on the one hand and on the other hand – to new forms of cooperation in the sphere of health care.

Sopharma invests predominantly in development of generic production, and it is expected that the role of the generic industry and sustainable health care in Bulgaria and in Europe will grow up. Generic medicines are means for optimization of the expenditures for health care and for the enhancement of the efficiency of the health care, providing access to efficient and modern treatment of more patients and releasing funds for creation of new medicines. The Governments pursue policies for use of generic medicines and simultaneously the demographic characteristics of the population in Europe predetermine the increased demand of medicines, in particular for chronic diseases.

The enhanced competition and the development of the science, inclusive of the bio-equivalent medicines create new forms of cooperation: co-marketing and co-development activities; contracts for workmanship; licensed production.

Initiatives for encouragement of the successful competition start up worldwide:

Revocation of patents for third countries to render assistance to the generic products in the EU to be competitive against the generic companies from Canada, the USA and Japan;

Signing an agreement for mutual recognition of the inspections of the production sites for drugs for human medicine between the USA and the countries from the EU which should finally enter into force for all the member-states of the EU up to year 2019

## 2. Employees

Sopharma AD invests in its employees with the conviction that they are its most valuable asset. As a responsible Employer the Company follows up certain principles of labor interrelations:

- Zero tolerance to any kind of discrimination at the workplace;
- Provision of healthy and safe working conditions
- It provides possibilities for development based on equality per gender and age
- Provision of a right of affiliation and labor protection of the employees

Due to the nature of its activity Sopharma guarantees the safe and health working conditions following the standards of the GMP. Along with that, the Company provides its workers and employees with workplaces corresponding to their knowledge and skills. The highly technological production as pharmacy nowadays is, assumes their continuous enhancement and expansion which for Sopharma is an investment in a significant asset. The programmes for enhancement of the qualification and the courses, which the Company offers to its employees, aim at the increase of their level of competence (number of trainings)

As a part of its social responsibility Sopharma introduced a system providing fair payment of the expended efforts and stimulation of the workers. A direct timely system for actual time worked out and additional material stimulation of the main workers on the basis of a monthly evaluation for manufactured and reported production of quality has been applied in the Plant for Ampoule Dosage Forms since 01.03.2017. The additional material stimulation reaches 30%. The introduction of a similar system for payment is forthcoming in the Tablet Plant as well.

Sopharma AD will offer its shareholders to hand out bonuses to their employees in the form of shares as a part of its programme for corporate social responsibility. So the even better presentation of the team and the development of investment culture will be stimulated, according to the words of Ognyan Donev.

Beyond its direct commitments as Employer Sopharma creates and develops social projects and programmes and participates in collective such directed at the employees and at their communities.

- Healthy life:
  - Additional health servicing
  - Gratuitous dental services
  - Availability of nurses in the plants of the Company
  - Annual gratuitous examinations by specialists
  - Fitness free of charge
  - Courses in folk dances free of charge
  - Inclusion in the programme for physical activity Multisport

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- Conduct of a children's camp in tennis
- Activities related to the mobile application @Healthy
- Provision of the employees with possibility to visit free of charge the forums "Longevity" and the "Freedom to Be"

- Inclusion of the employees as @SopharmaTeam in various competitions:

Competition in tennis

Competition in cycling

Creation and active participation in the programme of the Global Compact Network Bulgaria "Healthy at Work" with the pilot project "Games for Good". The Project includes a competition of teams from the companies participants in football, tennis, cycling and volleyball.

- @SoSociety, SoSopharma
- Gratuitous kindergarten on the territory of Sopharma for children of the employees of the Company;
- Assistance for each first year pupil – a rucksack with all the needed aids
- A baby set for each new-born baby
- Creation and active participation in the programme of the Global Compact Network Bulgaria "Proud of My Parents' Work", in which children of the employees visit the place of work of their parents and learn about the value of labor as a manner for creation of welfare
- Gratuitous library
- Maintenance of accessible and modern recreation bases of the employees in Vrabevo, Boboshevo, Pomorie and Ocharov Plazh (Shepherd's Beach)

**2017. Sopharma celebrated five years from the creation of the kindergarten in the Company for the employees in Sopharma AD!**

### **3. Ecology**

Sopharma AD stands up for and observes its commitments in conformity with the national legislation in the sphere of the preservation of the environment. The Company applies measures for:

- Separate collection of the wastes, minimization, utilization and recycling of the production and domestic wastes

- Provision of appropriate training of the personnel on issues related to the preservation of the environment and the prevention of pollution.
- Satisfaction of the imperative requirements of Decree of the Council of Ministers 137 and of the Ordinance on Packages and Wastes of Packages
- The emissions of waste gases in the ambient air from the Phyto-Chemical Plant and the Plant for Solid Dosage Forms are annually measured.
- Monthly Sofiyska Voda (Sofia Water) measures the emissions in the waste waters on the production sites A and B.
- The production wastes are handed over to licensed companies for recycling.
- The conditions from the Permit for Bellmouthing are satisfied.
- Once a month a report is made for the input and/or put onto the market packages in conformity with the kind of the material, which a monthly installment is paid for in Ecobulpack AD, which Sopharma AD has a contract concluded with, for utilization of the wastes from packages.

The plants of Sopharma are certified under the GMP, which also controls the degree of pollution of the environment. The emissions of waste gases are under 50 tons per year, which in conformity with the standards heads for 0.

Organic substances for filming the tablets have not been used in the production in the plants of the Company for years now, which guarantees the zero contamination of the waste waters. In parallel with this the use of a water film is a prerequisite for the non-emission of gases into the atmosphere.

## **4. Society**



### **Local Societies Местни общности**

Sopharma AD invests in its local manufacturing sites to protect the economic livelihood of local communities. Traditionally the company was a supporter of different projects in Vrabevo such as trading center with a pharmacy store and a restaurant; St. Archangel Mihail church's roof repairs.

Sopharma AD invested in another 5 guest houses in Vrabevo as a base place for employees' holidays and there will be 7 guest houses.

Sopharma AD works with Veliko Tarnovo municipality starting with projects for donations of medicines for clubs for elderly and retired people, but the program was outspread to investments in renovations of the clubs, donations for the community centers, free computers for the outstanding students of the Military University in Veliko Tarnovo, etc.

In 2017 Sopharma continue with donations of medicines and tools for health indicators measurement.





## Citizens

### **We're changing the city we live in**

#### **"Zdravi" eco-bicycle parking rack**

The "Zdravi" innovative eco-bicycle parking rack was opened during the closed competition of the European Tennis Tournament of NTCveterans. It is the first one of a series of bicycle racks part of #sopharmabike project. The "Zdravi" bicycle parking rack is designed for 12 bicycles and is placed near the tennis courts in the Kniaz Boris Garden. The next one was opened in front of the National Library St. Cyril and St. Methodius.

### ***Open air office***

A joint project with Foundation Credo Bonum, which turns an open air area into a space for shared work. The office is at the disposal for everyone who wants to replace the usual office by urban nature. The open air office offers all the conveniences there are at the workplace – high speed wireless Internet, electric power supply for the equipment, portable solar chargers for the mobile devices, recreation places. In parallel with this there is an organized programme with working breakfasts and discussion on various topics, presentations of companies, NGOs and actors in the office. The Project is implemented for the second consecutive year.

### **Christmas in Sopharma**

For the second consecutive year the Company organizes a Christmas holiday for children which is accessible for everyone willing to bring his/her child/ren/. The holiday includes Jazz for Children with Ventsi Blagoev, who provides the children themselves with possibility to be participants in the performances and workshops "The Dwarfs of Father Christmas" for paintings and coloring figures.

### **Reading fairy tales**

In 2017 Sopharma AD organized for the first time "Fairy Tales in Sopharma", which met authors of children's books and actors with the little readers and their parents. SBT were turned into a magical place for reading fairy tales along with the actors Ivaylo Zahariev, Yoanna Temelkova and Simona Halacheva and the author of children's books Radostina Nikolova and the illustrator and author Maya Bocheva. The older children got involved in the writing of own books with Maya Bocheva from atelier "This and That"

In a separate corner the guests and the participants will view hand-made souvenirs which they may buy and the funds raised will be donated for a charity cause.

### **Presentation of the book "Healthy"**

The children's book "What Is There in My Lunch Box" published by Sopharma under the Project "Healthy" presents to the children in an understandable manner the products which are contained in the usual things from their daily menu and where the products themselves come from. The book was presented during the day announced as "With Children at Work" through

interesting experiments and activities on the subject-matter healthy way of life prepared by Bio Igri (Bio Games).

Zdravi, Bio Gems and Muzeiko run „**The Human Body**” project for children of Sopharma employees. , during which different processes that occur in the human body - how to distinguish carbohydrates from proteins and where they are contained, etc., were shown once a month.

### **Pharmaceutical Industry**

The European industry for generic and biosimilar medicines fulfils its mission by providing high quality medicines for patients in Europe, increasing their access to effective treatment and partnering for sustainable healthcare. The generic and biosimilar industry is developing a model for sustainable pharmaceutical innovations associated with the development and manufacture of value-added products that can improve health outcomes and efficiency in hospitals.

Sopharma actively participates in the work of “Medicines for Europe” and in 2017 it got involved in various meetings and international conferences. A representative of Sopharma AD in the Executive Bureau of MEDICINES FOR EUROPE for the third consecutive mandate, which is a recognition for the vigorous activity of SOPHARMA as a full member of the Association and simultaneously one of the fastest developing regional leaders in Central and Eastern Europe. Sopharma participated in discussions during the Health Roundtable held in February 2017 at Marinella Hotel and in Innovation and Good Health Practices in October 2017 in Sheraton. The digital platforms #Healthy and #ExSmoker were presented at the Digital Transformation Pharmacy 3.0 forum, which presented the latest trends in the digitalisation of healthcare.

### **Partnerships**

#### **Bulgarian Network of Global Compact**

As an active member of Global Compact Bulgarian Network we Sopharma AD participates in joint projects of the Network “‘I Am Proud of the Work of My Parents’, ‘The Road of the Food’, ‘Responsible choice’ and ‘Healthy at Work’

**“I Am Proud of the Work of My Parents”** was held for the fourth consecutive year in Sopharma, and in 2017 the factory in Kazanlak was included. In 2017 21 companies participated in 19 cities across the country and 115 jobs have been shown from more than 15 sectors of the economy. The meaning for businesses is to show to the children of their employees through specially designed programs and games that their work is important.

The “**Responsible Choice**” Project aimed to show that the companies can, through transparency in responsible production and supply, demonstrate to the consumers that with their actions have the power to change the production practices, to influence the „fashion“ imposed by advertisers and to nurture anticonsumerist culture in themselves and young people.

#### **“Healthy at Work” Games for Good**

“Healthy at Work” is a programme for building up healthy habits and way of life of the employees of the companies through sharing good practices and information. The pilot project “Game for Good” includes a competition of teams from the companies participants in competitions in football, tennis, cycling and volleyball.

#### **BCause**

Sopharma AD joined the “Get Ready to Succeed” charity program of the **BCause** for the third consecutive year. The program has been helping excellent parentless students from high schools and universities to continue their education. The company chose to support two future medic and/pr pharmacys because pharmacy and medicine have always been inextricably related. “Doctor” and “Pharmacist” are among professions that could not develop without people’s trust, and together, they restore the most valuable asset in life – health.

#### **Rinker Academy**

From 2016 Sopharma supports the training programme Rinker’s Challenge for starting up traditional and social entrepreneurs of Center "Rinker" to Foundation BCause. Its first edition was in 2014. Rinker’s Challenge offers a unique possibility to starting up entrepreneurs to pass through a structured system of trainings, to receive personal advice from leading professionals and entrepreneurs in all the spheres of the business and to obtain start-up financing of their business projects.

#### ***Optimum Health, Maximum Vitality***

Sopharma AD supports the idea that health is not a lifestyle issue, but the only up to date and conscious way of living. That’s why Sophrama AD invests in programs and activities, including digital, related to health.

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#### **Social disease responsibility**

#### **Affordable treatment for smoking cessation**

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***According to latest scientific researches from around the world Sopharma' product Tabex® is best choice for smoking cessation treatment.***

## **2018**

### **Sopharma's smoking cessation drug with positive preliminary clinical data in the US**

Sopharma's (3JR BU) smoking cessation drug with positive preliminary clinical trial data in the US, the Company's American partner Achieve Life Sciences (NASDAQ: ACHV) announced in a statement.

Achieve acquired the rights to commercialize Sopharma's Tabex in the US in 2015. In 2017 it initiated an Investigational New Drug application with the US Food and Drug Administration and commenced a cytisine clinical development program in preparation to initiate a Phase 3 trial in the US in 2018. Sopharma is to be exclusive supplier of cytisine API and finished product under an up to 20-year exclusivity supply agreement.

Now Achieve announced positive preliminary data from the Cytisine Phase I/II Multi-Dose clinical study initiated in October 2017. Following the completion of the phase, the study evaluated the repeat-dose PK and PD effects of 1.5mg and 3mg cytisine in 24 healthy volunteer smokers aged 18- 65 years when administered over the standard 25-day course of treatment. The PK results indicated expected increases in plasma concentration between the standard and higher doses of cytisine with no evidence of drug accumulation. Furthermore, Cytisine was well-tolerated and reported adverse events were mostly mild and short-lived. Dr. Cindy Jacobs, Executive Vice President and Chief Medical Officer at Achieve said that the abstinence rates observed with cytisine were particularly impressive given the short 25-day treatment period. He also added that subjects did not commit to quitting and received only minimal behavioral support. Dr. Jacobs said that setting an actual quit date and receiving enhanced behavioral support were key factors to improve smoking cessation outcomes.

### **2017 starts with good news concerning the registration and further development of Tabex.**

The buyer of the share of Sopharma AD in Extab – Achieve – is undertaking a merger with another strong player in the development and registration of innovative medicines – Oncogenex, a publicly traded company on NASDAQ (<http://in.reuters.com/article/idINFWN1EV0QP>). The procedure is expected to be completed by mid 2017 subject to approval from the US FSC. Sopharma AD will own approximately 3.5% in the newly created company, which will aim at filing the IND for Tabex in 2017.

### **The new beginning**

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.

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

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

### **Events**

#### **Tennis Day with Sopharma**

The Bulgarian National Tennis Center and Sopharma AD organized jointly a Tennis Day with Sopharma sports festival for company employees and their families for another year.

Sopharma AD also provided a free tennis camp for the children of its employees. With coaches and all-day special program, the children acquired new skills in a healthy environment, new friends and positive emotions.

#### **Sopharma supports Velorali DRAG Cherni Vrah MTB race**

More than 150 people took part in the 14th edition of on 21st October. The route covers 38 km from Sofia's Boyana district up to Bulgaria's 4th highest mountain peak Cherni Vrah at 2290 meters, and back down again to the starting point. Sopharma traditionally supports the Velorali.

### **Digital Social Responsibility**

Sopharma communicates actively with her stakeholders through its new corporate site [www.sopharmagroup.com](http://www.sopharmagroup.com) for the Sopharma pharmaceuticals group. For the first time Bulgarian public company includes interactive instruments for investors and stakeholders related to company shares and group structure.

The company communicates with all its stakeholders through new digital instruments and support digitization of healthcare system. Sopharma AD supports public communication development as a building block of every democracy. Sopharma AD goes beyond the borders of traditional pharmaceuticals investments and support healthy and long living forums and festivals.

In digital era Sopharma AD provides all kinds of information, related to our products and different kind of health problems and health care through our digital channels. The company communicates through Sopharma AD' youtube channel and company profiles in facebook and twitter. Everyone can find us not only through our corporate profile, but using our different profiles related to different themes #Zdravi, #Silenden, #Ilovemyheart. The company created two different apps - #Exsmoker and #Zdravi. #Zdravi (means Healthy) - a social platform, that include a mobile application, blog and a facebook society, active not only in all social media but also offline. #Zdravi aims to create social commitment giving advices on physical and mental health and focus the attention on healthy living. Sopharma AD wants to show that "healthy" does not mean "boring" or "tough". Mobile app #Zdravi won first "Digital Oscar" award for online project and the awards for online project and CSR for business sector of Bulgarian PR Society.

**Investments in new communication channels, development of mobile apps Sopharma AD**

Sopharma communicates not only through its corporate website but also through its profiles in facebook, twitter and instagram. The company also created its own blogs related to health and positive thinking: [www. healthynewsmedia.bg](http://www.healthynewsmedia.bg), <http://silen-den.blogspot.bg/>. Sopharma AD supports for the 7th year “Just be” festival for healthy living and self development and first edition of The Long Living forum

**Investments in public communication development**

Sopharma AD is a long-term partner of the Bulgarian Public Relation Society, Medimixx platform and Annual Meeting of Bulgarian Media Abroad.

For the 6th year Sopharma AD supports Mediamixx - a platform for media communication and development. As the one of the kind platform in Bulgaria and its role in the society the festival brought together representatives from major Bulgarian media. This year Mediamixx is going beyond the national themes and borders and includes participants from South Eastern Europe. In 2017 Sopharma supports for another year the meeting of the Bulgarian media abroad, which was held in Belarus in 2017.

Sopharma monitors the following risks, identified as significant and potentially affecting its activities:

- Risks related to the macroeconomic situation in the country and other markets
- Risks related to the markets in which the Sopharma operates
- Risks related to foreign exchange rates and the currency board in force in Bulgaria;
- Currency risk

They are presented in detail in a report on the activity of Sopharma for 2017


**Non-financial Declaration to the Annual Financial Statement of Sopharma AD according to the requirements of Articles 48-52 of the Accountancy Act**

<b>Risk</b>	<b>Low</b>	<b>Medium</b>	<b>High</b>
<b>Socio - political</b>		<p>Loss of confidence in media (consumers also stop believing the ads included or additional info);</p> <p>Reducing the macroeconomic stability: The unstable political situation in Bulgaria and countries in which Sopharma operates may affect the company's activities;</p> <p>Decline in foreign investment</p> <p>Household indebtedness</p>	<p>The reputation of Sopharma AD may be affected by misleading or incorrect information in media;</p> <p>Changes in legislation and regulations may lead to a Group's expenses increasing</p> <p>Loss of confidence in the expertise of doctors or pharmacists</p> <p>Restrictions on household consumption, including for medicines</p>
<b>Employees</b>		<p>Fluctuation due to the highly competitive market</p> <p>Pressure to raise salaries and social benefits</p>	<p>Shortage of skilled workers with experience</p>
<b>Ecological</b>	<p>Environmental risks are minimized as a result of GMP and other standards</p> <p>Potential risk as a result of natural cataclysm</p>		
<b>Anticorruption</b>	Standart оператинг	An attempt for	

**Non-financial Declarastion to the Annual Financial Statement of Sopharma AD according to the requirements of Articles 48-52 of the Accountancy Act**

	procedures for decion making	involving to non-transparent practices on the part of monitoring institutions Unethical competition	
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27 March 2018  
Sofia

  
**Ognian Donev, PhD**  
Executive Director

