

"SOPHARMA" AD 28 March 2022

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# Statement of support

Dear partners,

We bring to your attention the Non-Financial Declaration to the Annual Financial Statements of "Sopharma" AD for 2021. The document describes the policies that the Company follows as a corporate citizen with an active and responsible attitude to the footprint of its activities.

We have continued to build the foundations for a sustainable future by improving the organization of work and changing the structure of our teams in the strategic areas. We invited international experts with established experience to work together with us to affirm the already well-known face of Sopharma as a reliable and trusted partner. We are already seeing results and this encourages us to take the next step forward towards a new and modern model of business that goes hand in hand with the nearly 90 years of history that has been created with hard work and consistency by all those before us.

The results achieved in 2021 bring us peace of mind as we see an emerging recovery trend in most of our markets. Particularly remarkable is the performance of the local market with a growth of 14% as a result of the optimization of a number of business processes and improving the performance of our main products.

We have set ambitious goals that build on experience, sustainable operations and create shareholder value for the long term. We realize that the social role and responsibilities of companies are becoming an increasingly important factor of impact and we strive for corporate social responsibility to be integrated into all processes and organizational aspects of the life of "Sopharma" AD.

This 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 impact.

Your sincerely,

Ognian Donev, PhD

# **About the Declaration**

The Consolidated non-financial declaration ("the Declaration") describes the commitments that Sopharma Group, as a corporate citizen, fulfills for the shareholders and investors, state and local authorities, consumers, customers and partners, the environment and society. The Group maintains an active dialogue with all of them in defining important decisions and in carrying out its corporate communications at all levels. Group companies monitor and declare the economic, social and environmental footprint that results from their activities. The measures used are in line with the main activity of the companies and are used to reduce the negative and increase the positive impact on their stakeholders.

The declaration complies with the reporting requirements of Art. 48 of the Accounting Law and is a description of the policies and enterprises regarding their activities in the fields of ecology, social affairs, employees, anti-corruption, human rights.

All companies in the Group strive to introduce good practices followed by the parent company "Sopharma" AD.

# Scope of the Declaration

The Declaration gives a broad overview of various aspects of the activities of "Sopharma" AD as a corporate citizen. It focuses on the company's activities for the period 01.01.2021 - 31.12.2021. The declaration contains quantitative data used as impact indicator in the main areas described below.

# Vision, strategy and corporate governance

# Mission, values, goals and strategy

The mission of Sopharma Group is to play an active role in raising people's living standards by providing constant and easy access to the most important health-related products.

To ensure the fulfillment of its mission, Sopharma Group constantly invests in production – new technologies, research and studies; in increasing the efficiency of distribution; in maintaining an active and effective dialogue with all participants in the healthcare system; in participation in significant projects and programs related to the development of society and in environmental protection.

The vertically integrated model of companies operating mainly in the field of healthcare supports the application of global and European standards and practices. Consolidation in the

Group leads to profitable synergies, better organization, centralization of major marketing and sales activities, cost optimization and better performance in all markets.

The parent company, as a leading pharmaceutical manufacturer, follows the best practices in the field of corporate citizenship. The values that logically determine life in the company and the interaction with the stakeholders are related to the care of people's health not only in the physical aspect, but also in emotional and mental terms.

The Sopharma Group's development strategy turns the companies into an attractive investment thanks to the following long-term goals:

- Portfolio diversification, expansion of foreign markets, successful acquisition operations;
- Sustainable development and strong performance in key markets;
- Transparent and efficient management model.

The results of the Group's work are always in favor of all stakeholders, making it a preferred "partner" in health and investment.

The Group is represented in over 45 countries with key markets in Bulgaria, Russia, Ukraine, Kazakhstan and Poland and a strategic plan focused on further market expansion in the region.

#### Corporate citizenship policies

The corporate citizenship of the Group operates and develops in accordance with the constitutions, laws and regulations of the countries in which the Group is active. In all its actions, the companies comply with the regulations of the state, local government and regulatory authorities and monitors the updating and strict implementation of the legislation concerning its activities. The Group follows the 10 basic principles of the UN Global compact and works towards the achievement of the Global sustainable development goals SDG 2015 through the active involvement of their companies in related projects.

#### Management systems

#### Corporate governance systems

Each of the companies operates following its basic internal rules, such as the regulations, and complies with its management systems in accordance with the imposed legislative and regulatory requirements. More specific management systems, related to pharmaceutical production and distribution are:

Coroporate	Description	Adoption	Last update
governance systems		date	
,			

the requirements	of Articles 48-52 of the Accountancy Act - 2021		
Prospect	The prospectus contains detailed information about the issuer of a financial instrument and about the issue itself.	2021	2021
Articles of Association	The Articles of Association determine the basic rules according to which significant decisions are made concerning the existence of the Company.	2003	2021
Decisions taken at the General Meeting of Shareholders	The decisions of the shareholders are fundamental for the activity of the Company.	at least once a year	2021
Code of conduct of the board of directors	Instructions and explanations for the duties and responsibilities of the members of the Board of Directors.	2007	2021
Good corporate governance program	A system of rules protecting the rights of shareholders and other stakeholders.	2009	2021
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 manufacturing.	2003	2021
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 distribution. The quality of medicinal products may be affected by a lack of adequate controls.	2003	2021
ICH "Q8 Pharmaceutical Development"	Principles and examples of Pharmaceutical Development.	2004	2021
ICH "Q9 Quality Risk Management.	Principles and examples of tools of quality risk management.	2006	2021
ISO 17025	General requirements for the competence of the laboratories for testing and calibration.	2014	2021
ΑΧΑΡΤΑ	ERP - program, which is an integrated information system for the overall business management of production planning processes, supply chain management, sales management and planning, financial management and control, customer relationship management, business analysis and more.	2013	2021

Internal Insider	Instructions and clarification on the obligations and	2007	2021
regulations	responsibilities with regard to in connection with the Law on		
	the Implementation of Measures Abuse with Financial		
	Instruments.		

#### Detailed description of the corporate governance systems:

#### The program for good corporate governance

A system of rules protecting the rights of shareholders and other stakeholders concerning the timely and accurately disclose information on all material issues related to the Company and to support its strategic management. The program also provides control over the activities of the Board of Directors/Management and Supervisory Board and its accountability to the company and shareholders.

The program is in accordance with current legislation, to the internationally recognized standards for good corporate governance and the Bulgarian National Code of Corporate Governance.

#### GMP

Good manufacturing practice is a system of rules and procedures which guarantee the high quality of medicinal products at every stage of their manufacturing. Its major purpose is to protect the patient's health. The GMP deal with both the production process and the working conditions, the qualifications of the production personnel, the sales system in use and the method of product withdrawal from the respective market.

#### GDP

GDP include an array of tools used in the activities of wholesale distribution, including preventing counterfelt medicinal products from entering the supply chain. Their implementation ensures control an efficient contor of the distribution chain and the maintenance of the high quality and integrity of the manufactured medicinal products. The GDP is applicable to any and all activities including the supply, storage, delivery or export of medicinal products, excluding the sale to the end users.

This system also includes competency of the employees, working conditions and product retention, control at any point in time to the final delivery.

#### **ICH Q8 Pharmaceutical Development**

The standard applies to the overall process of creating new products, from development to registration. It also includes risk assessment and quality assurance systems as part of product design. It concerns all components of the medicinal product, substances, excipients, active substances, development of the formulation and process of creation, knowledge accumulated during this process, physicochemical and biological properties, development of the manufacturing process and all information that may affect the final result.

#### ICH Q9 Quality Risk Management

Principles and tools for risk management that can be applied to all aspects of pharmaceutical products – creation, production, distribution and verification of life-cycle processes of substances and medicinal, biological and biotechnological products, including raw and supplementary ingredients and materials used for packaging and labeling.

ICH Q9 together with ICH Q8, serves to promote the development of science-based and risk-based approaches to quality. 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 competence requirements related to the competence of the testing and/or calibration laboratories, including sampling. The standard is intended to be used by laboratories that set up their quality control systems for both the administrative and technical activities. The results (protocols, certificates) issued by the accredited laboratories are used by regulators, 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 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.

#### ISO 9001:2015

The implementation of the Quality Management System to the requirements of ISO 9001: 2015 ensures the company's ability to continuously provide services that meet the customer's and applicable legal and regulatory requirements. Effective implementation of the system leads to increased customer satisfaction.

#### ISO 14001:2015

Through the implementation of the standard, the company is committed to the rational use of natural resources to ensure constant control over the identified aspects of the environment that it affects. Measures are implemented to manage the environmental aspects, those that can be controlled and those that are expected to have an impact on the part of the company.

#### OHSAS 18001:2013

Through the implementation of the standard, the company demonstrates its commitment to the health of its employees by providing a safe working environment, managing and minimizing the risks to the health of the personnel as well as to the staff of the stakeholders who work at the company's premises.

#### ISO 27001:2013

By applying the requirements of the standard, the company provides adequate and coherent security mechanisms, whose **purpose is to protect the information assets of the company and to ensure the confidence of each** interested party with special attention to the clients.

#### ISO 13485:2016

The standard specifies the requirements for a quality management system when an organization needs to demonstrate its ability to provide medical devices and related services that consistently meet customer requirements and applicable regulatory requirements.

#### БДС INISI / IEC 17025

Laboratory Block BSE, DZG is an accredited laboratory according to BIS INISI / IEC 17025 by the Bulgarian Accreditation Service (BSA) and has the right to carry out tests which are recognized by all national and European food control authorities. The scope of accreditation includes tests of foods of different origins; water and beverages; feed; control of technological surfaces and carcasses; Diagnosis of diseases in all species of domestic and wild animals; bees and a beehive.

Since 2014, the Lab Unit has been housed in new laboratory premises including Biosafety Level 3 for disease diagnosis as required by the OIE.

#### **CE BRAND**

Conformity of Medical Device Directive 93/42 / EEC.

#### ΑΧΑΡΤΑ

Integrated information system for business process management in the corporate activity of the high class company.

It improves efficiency, helps to make more precise decisions, and improves interconnections with the supply chain.

It supports sales management and planning, production to material planning and production capacity, supply chain management resoursec — stocks, warehouses and links between them, quality management.

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

#### World Health Organization Good Distribution practices (WHO Technical Statement Series, No 937, 2006)

By applying the requirements of the European Commission described in Directive 2001/83 / EC, the Management Manual of Good Practice of Distributing Practice of 5 November 2013 and the World Health Organization, the companies engaged in distribution declare their expertise and constant control over quality assurance, ensuring that products consistently stored, transported and handled under appropriate conditions as required by the marketing authorization or product specification.

# Imprint of the company's activity

# **Economic impact**

#### We create added value for our stakeholders

Shareholders and investitors	State and local authorities	Clients and partners	Environment and society	
Economic and financial data	2021	2020	% change	Stakeholders
			(100)0	
Decision for payment of dividends by the General Meeting in the amount of BGN per 1 share	-	BGN 0.04 for the first half	(100)%	Shareholders
Taxes paid in thousand BGN Incl:	11 994	9 488	(26.41)%	State and local authorities
Taxes paid (other) in thousand BGN	7 939	5 220	(52)%	
Corporate tax paid in thousand BGN	4 055	4 268	(5)%	
Payments to suppliers in thousand BGN	104 150	118 969	(12.47)%	Suppliers /including hired services/
Payments for wages and social insurance in thousand BGN	44 657	48 807	(8.5)%	Employees

The economic footprint is most clearly tracked through dividend decisions that show the relationship with stakeholders as shareholders; paid taxes, incl. paid corporate tax, which is a contribution to state and local authority; payments to suppliers showing relationships with companies in the supply chain; the cost of labor that shows employee relations as an interested party.

# Social Impact

# We promote the development of health culture and invest in civil society

Economic and financial data	2021	2020	Stakeholders
Plants / Number of employees	8/ 1768	9/ 1 991	Work places - employees
Fights / Number of employees	0/ 1/00	5/ 1 5 51	work places - employees
Training courses /expenses BGN '000/	111	123	Employees
Social benefits and payments /expenses BGN '000/	2 024	2 037	Employees
Medical services /expenses BGN '000/	747	830	Employees
Donations /expenses BGN '000/	206	465	Employees, Local communities
Investments related to the development of the generic business sphere and the health system / number (sponsorships and participation in seminars)	-	15	All stakeholders
Investments related to development of the business environment (KRIB, ABIRD etc.) / number	2	9	All stakeholders
Investments to sport and healthy lifestyle programs / number	-	14	Society
Investments in public communications /number	-	3	Society

# Projects related to promoting health culture and investing in civil society.

"Sopharma" AD works to increase the economic and social development of society, to promote a healthy lifestyle and to improve the health culture.

The company holds on to traditions that nurture fundamental values, such as health care in harmony with nature, strengthening the community and nurturing the competitive spirit.

- Supporting various sports activities and competitions:
  - Support for the International Cycling Tour (ICBM) of Bulgaria

- Sponsorship of the European Cycling Championship
- Sponsorship of the Bulgarian Federation of Sports Acrobatics and support of a competition from the World Cup of Acrobatics for children and youth
- UN Global Compact Network Initiatives "Games of Goodness" Supporting sport with a cause: collective, individual or virtual games
- In 2021, efforts were made to provide a safe environment for employees and partners in a COVID-19 pandemic situation. In the face of pandemics and difficult deliveries, measures were introduced to prevent the lack of vital medicines, medicines with increased consumption and directly related to the treatment of COVID-19.
- Investing in new digital communication channels to help society tackle smoking.
- **Tabex Application** a tool for creating community, advice and mutual support between people who want to quit smoking. The application is installed by 10 540 people for a period of one year.
- Creation and development of 3 product pages with up-to-date product information and long-standing advice to the public.
- Donations to hospitals, Bulgarian Red Cross, homes for the elderly.

## **Ecologic impact**

#### Responsible use of resources and environmental protection

Indicators	2021	2020	
Cost of raw materials (electricity, headenergy, fuels, water; without main materials, waste and impairment)	16,859	16 305	
/expenses BGN '000/ Costs for transport services	3 181	3 570	
Separate waste collection	442 tons	1 700 tons	
Exhaust emissions into the atmosphere	0*	0*	
Emissions to wastewater	Waste water is treated in WWTP **		
Employees trainings and inclusion environmental protection activities in Instruction of employees;   Instructions for recovery and separate waste; Instructions on how to deal with waste in the units;   Participation of employees in an initiat Global Compact - Action to collect appliances for recycling.		and separate collection of leal with waste substances es in an initiative of the UN ion to collect household	

\* The plants of Sopharma AD are certified according to Good Manufacturing Practices (GMP), which also require control of the degree of environmental pollution. Emissions of waste gases are less than 50 tons per year, which according to the standards tends to 0.

\*\* For years in the production in the factories of the company no organic substances are used for filming the tablets, which guarantees zero pollution of the wastewater.

The main part of the turnover, operating and capital costs of the Company are related to economic activities that qualify as environmentally sustainable, with the exception of some transport activities by third parties and domestic transport activities, which increase / decrease by BGN 389 thousand in 2021 or by 10.9% compared to 2020.

Projects related to responsible use of resources and environmental protection

- Separate waste collection, minimization, utilization and recycling of production and municipal waste;
- Caps for the Future Charity collection of plastic caps at all production sites;
- Providing regular training of personnel on environmental issues and pollution prevention;

- Responsible implementation of the mandatory requirements of Decree of the Council of Ministers 137 and the Ordinance on packaging and waste;
- Switching from plastic to paper sticks in the production of ear sticks;
- Separate collection of household waste (paper, plastic, batteries) at the workplace. Containers provided at all production sites;
- Reduction of printed advertising materials by 50% per year until 2025, by switching to digital content;
- Annual measurement of waste gas emissions into the atmosphere;
- Monthly measurement of emissions into wastewater at production sites A and B of Sofia Water;
- Investments in the creation of "smart" buildings, facilities for renewable energy sources;
- Zero pollution of wastewater and the atmosphere, through the use of water film, instead of organic substances for filming the tablets in the production in the company's plants;
- Measurement of the annual emissions of waste gases in the atmospheric air from the Phytochemical Plant Kazanlak and the Solid Dosage Forms Plant Sofia.
- Creation and development of an internal Info portal with sections with training materials in support of employee development, special discounts and conditions from the company's trading partners and useful daily information about life in Sopharma.

# Employees

# We are focused on the responsible behavior of our employees and provide equal job opportunities

"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 for any kind of discrimination in the workplace;
- Ensuring healthy and safe working conditions;
- Ensuring opportunities for development based on equality;
- Ensuring the right of association and labor protection of employees.

# Safe working conditions

Due to the nature of its activity Sopharma guarantees the safe health working conditions following the standards of the GMP.

• For the jobs, professions and types of work for which Personal protective equipment is applied, including special work clothes, an order is followed, signed by the Executive Director of "Sopharma" AD - Ognian Donev, prepared according to Regulation No. 3 on Minimum Safety and Protection Requirements workers' health when using PPE on work place / Prom. State Gazette, no. 46/2001), Ordinance on free working and uniform

clothing (promulgated SG No. 9/2011) and in accordance with Article 284 of the Labor Code.

• For safe work with machines and equipment the operators follow the safety instructions with which they are familiar and obliged to follow. / Approved with the signature of the Production Director" /.

• Prevention of risk situations concerning the health of the employees - a three-month periodic briefing is conducted in all factories for employees in each section documented with the personal signature of the employee.

#### Workplaces corresponding to the knowledge and skills of employees

The funds invested in raising the qualification of employees (training) in 2021 amounted to BGN 111 thousand.

Beyond its direct commitments as an employer, "Sopharma" AD creates and develops social projects and programmes and participates in community events directed at the employees and at their families.

#### Healthy life:

- Additional health services;
- Availability of nurse in the plants of the Company;
- Annual free examinations by specialists;
- Fitness free of charge;
- Inclusion in the programme for physical activity Multisport;
- Involve employees in various competitions such as @SopharmaTeam: tennis court; cycling competition; participation in ultra marathons.

#### @SoSociety, SoSopharma

Indicator	2021	2020
Parental Care		
Employees that took parental leave	4%	4%
Employees that returned to work in the reporting period after parental leave ended	<1%	<1%
Employees that took unpaid parental leave	<1%	<1%
Employees that returned to work after parental leave ended that were still employed 12 months after their return to work	3%	3%
A baby set for each new-born baby/ number	43	50
Assistance for each first year pupil – a rucksack with all the needed aids/number	34	39
Free kindergarten on the territory of Sopharma for children of the employees of	28	22

the Company, opened 2012/number of children		
Leisure time		
Free library / number of employees using the services	60	70

# Structure of employees by gender 2021 (2020)

Gender of employees	2021	2020
Man	37%	37%
Women	63%	63%

# Structure of employees in education 2021 (2020)

Employees/education	Number	Relative share %	Number
	2021	2021	2020
Higher education	811	46%	891
Colleges	35	2%	41
Secondary school	899	51%	1 024
Elementary education	23	1%	28

# Structure of employees by age 2021 (2020)

Employees /	Number	Relative share	Number
Age		%	
	2021	2021	2020
under 30	148	8%	184
31- 40	300	17%	360
41 – 50	492	28%	574
51 – 60	643	36%	679
Over 60	185	11%	187

# Structure of the employees of the group of "Sopharma" AD in 2021

Employees	Total	Women	Men

Hierarchy		2021	%	2021	%
Top management	5	2	40%	3	60%
Senior Management	59	25	42%	34	58%

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

#### 1. Market

"Sopharma" AD is aware of its role of a significant factor in the pharmaceutical sector at a European level and in the Bulgarian economy.

As a leading 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.

"Sopharma" AD invests in the fields of science and development, quality management, industrial property, publicity and transparency.

The products and business model it creates, position "Sopharma" AD among the top 10 companies on the Bulgarian pharmaceutical market and first in terms of sales in units with a 10.5% of the market.

The group is represented in more than 45 countries, but the key markets are Bulgaria, Russia, Ukraine, Kazakhstan and Poland, and the strategic plan focuses on further expanding its presence in the region.

	Review of the results		
Key indicator	Unit	2021	2020
Market share in units	%	10.5	10
Market share in value	%	2.8	3

# The market share in units of the products of "Sopharma" AD as well as the share of the OTC products 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 of the products, as well as the adequate CSR (Corporate Social Responsibility) Strategy have an impact over the preferences by the end user at the point of purchase of medicines.

The positions of the main competitors of the company on the territory of the country are as follows: Novartis -7.04% (3.76% in units), Roche - 5.76% (0.14% in units), Merck Sharp Doh - 4.02% (0.13% in units), Teva - 3.90% (9.80% in units), Pfizer - 3.65% (0.69% in units), Abbvie - 3.34% (0.06% in units), Astrazeneca - 3.18% (0.48% in units), Bayer - 2.82% (1.97% in units),

Sanofi-Aventis - 2.72% (2.46% in units). The products with the largest share of sales in the country are Analgin, Methylprednisolone, Antistenocardin, Famotidine, Parecatamol, Buscolyzin, Allergosan.

#### **Production activity**

"Sopharma" AD has eight manufacturing plants in Bulgaria, which function in compliance with the requirements of the EU and of the Bulgarian legislation:

- 1. Plant for solid dosage forms, Sofia
- 2. Plant for solid, semi-solid and liquid dosage forms, Vrabevo
- 3. Plant for solid dosage forms, phytochemical and synthetic products, Kazanlak
- 4. Ampoule plant, Sofia
- 5. Lyophilic production, Sofia
- 6. Suppository plant, Sofia
- 7. Gamma sterilization, Sofia
- 8. Plant for medical products, solid and liquid dosage forms, Sandanski

"Sopharma" AD is the largest Bulgarian manufacturer of ampoules and suppositories and a sole manufacturer of lyophilic dosage forms in Bulgaria.

The production activities of the Company are realized and developed in the following areas:

- Substances and preparations based on plant raw materials (phytochemical production);
- Ready-to-use formulations, incl.: hard tablets, coated tablets, film-coated tablets, capsules;
- Galenic suppositories, drops, syrups, ointments, gels, creams;
- Parenteral injection solutions, lyophilisate powder for injections;
- Hemodialysis solutions;
- Medical and cosmetic products, incl.: plasters; dressing products; sanitary-hygiene products; herbal cosmetics.

#### Products

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

The Company has more than 200 products in its portofolio, mainly generics and 15 traditional products, of which 12 are plant-based.

Taking into consideration the responsibility related to its market position, Sopharma invests in new production capacities, technologies and products to achieve more effective treatment and in new digital applications for marketing its products:

Investments	2021	2020
Renewed Marketing authorizations / number	45	5
Documentation submitted for the renewal of the Marketing Authorizations medicinal products of agencies/ number	32	4
Pharmaceutical developments of medicinal products and active substances / number	18	11
Investments in new technologies / transferred and validated / number	19	30
Marketing authorizations for pharma products for new destinations / number	18	27
Cosmetic products, food supplements and medical devices notified / registered in Bulgaria and other countries	14	40

The Company invests in enrichment of the generic portfolio by working on the implementation of generics:

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

#### **Responsible marketing**

"Sopharma" AD pursues a flexible marketing policy, taking into account the possible increase of the delivery prices of the raw 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.

Activities are consistent with the Change Control Criteria (ICH Q10 3.2.3) and Material and Process Requirements under Good Manufacturing Practice (GMP) guidelines Part 1, with internal procedures approved in a standard operating procedure for change control and standard operating procedures on the approval of manufacturers of active substances, auxiliary substances, packaging materials, feedstock and are managed through an internal eDMS system. The selection and evaluation criteria cover quality criteria, regulatory compliance, certification status, documentation as well as economic, financial criteria and delivery parameters. Approved manufacturers and the implementation of deliveries are subject to continuous monitoring as part of the management of the purchase process.

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 ethical 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" AD invests mainly in the development of generic production and the role of the generic industry for sustainable healthcare in Bulgaria and in Europe is expected to grow.

Chairman of the Board of Directors and Executive Director				
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	
Business Development	Production	Finance	Market presence of "Sopharma" AD in:	
Trade Directorate	Resources	Logistics	Ukraine Poland	
Operational Directorate	Investor relations	Process efficiency and product quality	Kazakhstan Baltic States and Belarus Turkey	
Cooperation and licenses	Labor protection	Quality assurance	Azerbaijan Georgia	
Administrative Directorate	Human Resources	Development and regulatory compliance	Armenia Tunisia	
Intelectual Property	Financial and accounting department	Quality control	China Israel and the Palestinian Territories	
Legal Department	Technical Directorate			

# 2. Organizational structure

# 3. Company development

1933	First production building of the Bulgarian Pharmacy Cooperative Company	The pharmaceutical community united in its economic organization "Bulgarian Pharmacy Cooperative Company" starts the construction of the first production laboratory for production of medicinal products in the country.
1942	Pharmaceutical factory "Galenus"	The production laboratory of the Bulgarian Pharmacy Cooperative Company moves in a building especially constructed for its needs on "Iliensko shousee" and grows into "Galenus" – a pharmaceutical plant in which better conditions are a prerequisite for faster development. This leads to increase of production capacity and widening of the product portfolio. "Galenus" is the first modern industrial plant for production of medicinal products on the Balkan Peninsula, competing with popular German and Swiss companies.
1953	Chemical-Pharmaceutical Plant - Sofia	All machines for the production of solid forms are moved into the "Galenus" plant. The average production capacity of one machine reaches 5,576 tablets per hour. The main products are Aspirin, Chinin and Doverin produced with imported and high quality raw materials. In the same year, after the nationalization, the "Galenus" plant is renamed into Chemical-pharmaceutical plant – the ancestor of Sopharma.
2000	Privatization	After a successful privatization Sopharma becomes a private pharmaceutical company. The first years after privatization are a period of constant modernization and improvement. For the two years after the privatization period Sopharma unites six enterprises in a modern and dynamic corporate structure including: Sopharma AD, Unipharm ASD, Vramed AD, Pharmachim Holding AD, NIFHI AD and Rostbalkanpharm.
2003	Pharmaceutical plant "Sopharma – Vrabevo", which is fully compliant with the European standards for Good Manufacturing Practices (GMP)	The President of the Republic of Bulgaria George Parvanov officially opened the new pharmaceutical plant "Sopharma – Vrabevo". In this modern plant for production of medicinal products Sopharma invested 20 million BGN. Each step of the construction of the plant followed internationally accepted GMP (Good Manufacturing Practices) standards.
2004	Sopharma fully licenses its production capacities according to the European standards for Good Manufacturing Practices	In 2004 Sopharma licensed its production facilities according to the European GMP which secured its strategic position after the EU accession in 2007. In the same year Sopharma increased its production capacity by adding another member to its group of companies - Bulgarian Rose - Sevtopolis AD.

2005	Most modern Bulgarian logistics center	In 2005 Sopharma opened the most modern logistics center in Bulgaria (logistics terminal) for distribution of pharmaceutical products. The logistics center fully complies with the European Good Distribution Practice (GDP).
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.
2016	Consolidation and expansion	"Sopharma" AD acquires 68% of the capital of "Veta Pharma" AD.
2017	Consolidation and expansion	"Sopharma" AD acquires 51% of the capital of the Moldovan distributor of medicinal products RAP Pharma International. "Sopharma" AD acquires 75% of the successful start-up for the development and marketing of Aromania food supplements. "Medica" AD is merged into "Sopharma" AD.
2018	Consolidation and expansion	"Unipharm" AD is merged into "Sopharma" AD. The company celebrates its 85th anniversary.
2019	Expansion	"Sopharma" AD registered the first generic - "Urimax duo" in the field of urology.
2020	Consolidation and expansion	"Sopharma Trading" AD acquires sole control over the companies "SCS Franchise" AD and "Sanita Franchising AD, which strengthens its position on the pharmacy market." "Sopharma" AD sold the shares owned by it from the capital of "Aromania" AD, after having mastered all significant brands and activities. As a result of lengthy negotiations and an agreement reached with the other shareholders, a change in the shareholder structure of the subsidiary SIA "BRIZ" was entered in the Commercial Register of the Republic of Latvia as a result of which "Sopharma" AD remains the sole owner of the capital of the company. Marketing Authorization was obtained for 5 new medicinal products - Solifenax 5 mg film-coated tablet (Bulgaria), Ambrolitin 30 mg/5 ml syrop (Bulgaria, Latvia, Estonia), Ketoprofen 100 mg/ 2 ml solution for injection (Bulgaria), Sofazolon 40mg powder and solvent for solution for injection (Bulgaria), Dexketoprofen 50mg/2ml solution for injection (Latvia, Lithuania, Estonia).
2021	Consolidation and expansion	"Sopharma" AD realized a successful issue of warrants amounting to over BGN 12 million.

# 4. Risks

"Sopharma" AD monitors the following risks, which it has identified as significant and potentially affecting of its activities:

- Risks related to the macroeconomic situation in the country and other markets;
- Risks associated with the business and the industry in which the Company operates;

- Risks related to the markets in which Sopharma operates;
- Risks related to foreign exchange rates and the currency board in force in Bulgaria;
- Credit risk.

Risk	Low	Medium	High
Socio - political		Loss of confidence in media (consumers also stop believing the ads included or additional info); Reducing the macroeconomic stability; The unstable political situation in Bulgaria and countries in which "Sopharma" AD operates may affect the company's activities; Decline in foreign investment; Household indebtedness.	The reputation of "Sopharma" AD may be affected by misleading or incorrect information in media; Changes in legislation and regulations may lead to a Group's expenses increasing; Loss of confidence in the expertise of doctors or pharmacists; Restrictions on household consumption, including for medicines.
Employees		Fluctuation due to the highly competitive market; Pressure to raise salaries and social benefits.	Shortage of skilled workers with experience.
Ecological	As a result of certified production, environmental risks are minimized; Potential risk as a result of natural cataclysm.		
Anticorruption	Standart operating procedures for decion making.	An attempt for involving to non- transparent practices on the part of monitoring institutions; Unethical competition.	

#### **Responsible business and Transparency**

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

In the business strategy of "Sopharma" AD there is zero tolerance for any kind of corruption, employees are expected and required not only to act in a ethical manner, but also to combat corruption. We interact with all levels of government with our stakeholders and therefore have the right and responsibility to express our position of a corporate citizen.

# IV. Strategy for corporate social responsibility

# 1. Definition

For "Sopharma" AD responsible corporate ctizenship is 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 works hard to achieve UN's SDG 2015.

"Sopharma" AD actively communicates its activities with all stakeholders. The CSR strategy, initiatives and specific activities are planned and developed, coordinated and implemented by the Media and Advertising Manager, after obtaining the approval of the Board of Directors of "Sopharma" AD.

#### The policies and specific projects are focused on 4 main areas:

- Health and healthy lifestyle
- Compassionate business and care for the environment
- Education
- Community

#### Strategic Management

Market	Employees	Environment	Community	Corporate Citizenship
Transparent corporate governance	Responsible employer: Zero discrimination regarding the right to work	Environmental management systems	Contribution to economic development	Anticorruption
Guaranteed quality and safety of products and services	Ensuring the right of association	Reduciton of environmental impacts	Developing the healthcare system	Work on SDG 2015
Sustainability	Employee development: hierarchically and as a qualification and education	Responsible use of resources	Health prevention	Participation in the establishment and implementation of international pharmaceutical 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

of waste and environmental issues		nternal communication	
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## 2. Memberships

In order to adequately create and implement its CSR strategy, "Sopharma" AD works with partner organizations such as the BCAUSE 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" AD is member of :

- Confederation of the Employers and Industrialists in Bulgaria (CEIBG). http://ceibg.bg/
- Member-cofounder of the Association of Bulgarian Exporters (ABE), which 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/
- 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
- 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. www.iccwbo.org, http://www.icc-bulgaria.bg
- Member of UN Global Compact Bulgarian Network. http://www.unglobalcompact.bg
- Member of the National Corporate Governance Committee, established to promote the implementation of good corporate governance practices and the development of the Bulgarian National Corporate Governance Code. The Commission is a permanent independent body created under the auspices of the Bulgarian Stock Exchange (BSE) and the Financial Supervision Commission (FSC), with the support of the World Bank and the International Finance Corporation (IFC). www.nkku.bg

# 3. Commitment to stakeholders

From the point of view of "Sopharma" AD, an interested party is any group which is directly or indirectly related to the company's activities and has the potential to influence it and can influence the decision-making for the business development of the Company.

The relations with the interested parties are an indicator of the degree of success of the Company, of its place in the economic and social life in the country and an assessment of the viability of the adopted course for its development.



- Key stakeholders are the patients for whom Sopharma's products are a a remedy and means of improving the quality of their lives.
- Shareholders as a public company Sopharma AD recognizes its obligation to provide adequate and timely information about its activities in the field of CSR to all shareholders and potential investors in the Company.
- 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 the pharmaceutical 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 them.
- Local community "Sopharma" AD owns 8 factories in the country and is a major investor in some regions undertaking 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.

"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 Group website, the company's activity reports, the COP report submitted to the United Nations Global Compact and the newsletters published by the partner organizations. The informal communication channels include Sopharma profiles in various social networks, the company's mobile applications, etc.

"Sopharma" AD communicates to all stakeholders through different channels:

Stakeholders	Communication channels	Frequency of communication
Patients	Product websites; Official corporate sites of "Sopharma" AD.	Weekly; When there is new information; "Sopharma" AD uses the group's website to provide reliable information related to European generic associations; changes in the
	Website of the group www.sopharmagroup.com	regulatory framework concerning the end user, etc.
	Oonmonuum filos en ED lasterrem	Daily Daily
	Copmany profiles on FB, Instagram, Twitter; Social platform "Tabex"; mobile app	When needed
Shareholders	General Meeting of Shareholders; Notifications; Meetings; Sopharma's official corporate media - Website of the group www.sopharmagroup.com	Regularly
State and Local authorities	Participation in online forums dedicated to problems in pharmacy; Official sites of the state and local	Digital transformation in the pharma sector;
	authorities, of the control bodies; The official corporate media of "Sopharma" AD;	Forum on the markets in the Eurasian Union.
	Participation in working groups related to the healthcare system and	Every day
	pharmacy.	Regularly, depending on the program of the particular group
Chain partners	Business meetings.	Regularly
Employees	Intranet page; FB page of "Sopharma" AD; Corporate website of the Group www.sopharmagroup.com;	When needed Daily When needed

	New info page with inside information for employees; Bulletin boards; Internal mailing.	When needed When needed When needed
Society	Healthy life conferences; Public communication conferences; FB pages of "Sopharma" AD; Profiles on social media Instagram, YouTube.	Daily 4 conferences per year Daily Daily
Partners	Meetings and conferences; Business meetings.	Regularly

#### 4. 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 specific projects. The company supports the development of an active civil society in the country and takes firm positions on a number of socially important issues.

#### **Local Societies**

- "Sopharma" AD invests in its local industries to protect the economic life of local communities. Traditionally, the company was a supporter of different projects in Vrabevo such as a shopping center with a pharmacy store and a restaurant; St. Archangel Mihail church's roof repairs; local lyceum Christo Botev in Vrabevo, local lyceum in Sandanski;
- "Sopharma" AD works together with the Municipality of Veliko Tarnovo and the Bulgarian Red Cross with donations of medicines to homes for the elderly and pension clubs;
- In 2021 "Sopharma" AD continues with donations of medicines and tools for health indicators measurement, such as blood sugar;
- Donations for research in the fields of pharmacy and biology and support for the publication of a textbook;
- Donation of medicines (OTC and food supplements) of first necessity to the Center for Social Rehabilitation and Integration and the Day Care Center for the Elderly in Dimovo.

# Partnerships

# 1. Bulgarian Network of Global Compact

As an active member of the Bulgarian Network of the UN Global Compact, "Sopharma" AD participates in a number of projects focused on health and a healthy lifestyle.

#### Investments in public communication

"Sopharma" AD supports the development of public communications as a basis for any democracy. The Company works beyond the ideas of traditional pharmaceutical projects and supports forums and festivals related to longevity, healthy lifestyles, the development of public communications.

#### **Digital Social Responcibility**

"Sopharma" AD communicates with its stakeholders through its website: https://www.sopharmagroup.com/en and through product pages of focal OTC products and nutritional supplements. For the first time a Bulgarian public company provides interactive tools for investors and shareholders related to the shares of the Company and the structure of the group.

The Company communicates with all stakeholders through the new digital tools and continues to invest and develop its digital channels. The Company communicates through the Youtube channel of "Sopharma" AD and its profiles in Twitter and Facebook.

#### Pharmaceutical Industry

The European industry for generic and biosimilar medicines "fulfils its mission by providing high-quality medicines for patients in Europe, by increasing their access to effective treatment and partnerships for sustainable health". The generics and biosimilar industry is developing a model for sustainable pharmaceutical innovation related to the creation and production of value-added products that can improve health revenues and hospital efficiency.

The purpose of this document is to enable users of the information in it to feel the attitude of management to the sustainable development of the Company and its role as a corporate citizen.

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March

2022

Ognian Donev, PhD Executive director