Corporate Responsibility Report 2016 - 2017

Brief Version

<u></u> NOVARTIS

About this Report

This Report constitutes a brief version of Novartis Hellas' 2016-2017 Corporate Responsibility Report available at www.novartis.gr. This is the fourth edition of Novartis' Corporate Responsibility Report and it has been developed in "accordance-core" to the Global Reporting Initiative (GRI) Sustainability Reporting Standards (GRI Standards). The Report includes Novartis Hellas' Communication on Progress (CoP) against the United Nations Global Compact (UNGC), while its content has been set as defined by AA1000 Accountability Principles Standards. Finally, the full version of the Report reflects the company's contribution towards achieving the United Nations Sustainable Development Goals (SDGs).

Contents

2016-2017 Highlights	4
Message from the President & Managing Director	5
Profile	6
Supply Chain	6
Human Resources	7
Environmental Responsibility	8
Awards and Distinctions	8
Message from the Head of Communications	9
Corporate Responsibility Strategy	10
Stakeholder Engagement	10
Materiality Analysis	10
Patient Focus	12
Research and Development	14
Product Quality and Safety	15
Governance and Ethical Business Practices	16

2016-2017 Highlights

Total investment (tax payments, employee wages, R&D, Return on investment in the donations, sponsorships, social support **Greek Economy and Society** programs, rebates and claw back) 35% €293.1m No. 1 Pharmaceutical Company in Greece Turnover (by market share based on IMS data) 2017 → €329.4m **2017** → **9.1%** 2016 → €315.7m $2016 \rightarrow 9.4\%$ Amount invested in donations, sponsorships Tax payments and employee wages and corporate responsibility programs 2017 → €37.5m 2017 → €2m 2016 → €33.8m 2016 → €3.4m Investment in Research & Development (R&D) in Greece (clinical trials) Number of clinical trials in Greece 2017 → €7.6m $2017 \rightarrow 93$ 2016 → €7m $2016 \rightarrow 114$ Indirect purchases percentage Stock availability from Greek suppliers $\mathbf{2017} \rightarrow \mathbf{99.97\%}$ **2017→ 95.7%** $2016 \rightarrow 99.96\%$ $\mathbf{2016} \rightarrow \mathbf{97.6\%}$ Amount invested in cooperation with Greek Total number of patient associations pharmaceutical companies supported by the company 2017 → €15.9m 34 2016 → €20.6m Total employees number and male/female Percentage of female managers percentage **2017** → **58%** 2017 → 477 (54.5% F, 45.5% M) **2016** → **58%** $2016 \rightarrow 468 (54.3\% \text{ F}, 45.7\% \text{ M})$

Message from President & Managing Director

Dear readers,

Novartis Group operates in Greece for more than 20 years, with a rich portfolio including innovative medicines (Novartis), generic and biosimilars (Sandoz), as well as eye care products (Alcon).

The last two years were characterized by several challenges both for our company and for the pharmaceutical industry in general. We recognize as a negative milestone the reports regarding our business practices, in the past. Fully aware of the severity of the allegations, Novartis, with a sense of responsibility and integrity, is committed to taking all necessary action, in case, practices that do not comply with ethical business standards, are established.

Despite the challenges, we have managed to remain focused on our mission: to help Greek patients live longer and with better quality of life in a sustainable way, both for the Greek society and our company.

Within this framework, during 2016-2017, Novartis Hellas returned to the national economy €293 million, 35% of its total annual revenue, through investment in research and development, tax payments, including clawback and rebates, payroll, Greek suppliers support, donations and social programs.

More specifically, the company's investments for conducting 114 clinical studies in 2016 and 93 in 2017, reached \in 14 million. At the same time, we supported the Greek pharmaceutical companies through collaborations on co-promotion with investments of \in 35 million. In addition, the company retained its commitment to responsible supply chain management operation,

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maintaining its domestic suppliers' market share at 97.6% for 2016 and 95.7% for 2017, aiming to further strengthening the domestic market. In an effort to minimize the environmental impact of our activities, we implement recycling and carbon dioxide emissions reduction programs, while we achieved a reduction in per capita water consumption by 3.7%.

For all that we have achieved, the driving force has been the over 450 company employees who support our work every single day. We are deeply proud and thank them for their dedication and their responsibility to remain faithful to our company's values and to our focus on the sustainability principle.

In our 2016-2017 Corporate Responsibility Report, we report on the progress efforts, we have made during the reporting period, to improve our performance, with regards to the responsible management of our sustainability material issues relevant to our operation. Our Report consists of four key thematic pillars: Patient Centricity, Research and Development, Product Quality and Safety, Governance and Business Ethics.

These four pillars include all the information that reflects our patient centric approach, as well as the effort we make to ensure that access to effective treatment methods will be possible for everyone. The combination of science and responsibility helps Novartis Hellas build trust and create value for the company, its stakeholders and the wider society.

Thank you for reading,

Susanne Kohout President & Managing Director Novartis Hellas

Profile

The Novartis Group

Novartis is a multinational pharmaceutical company, headquartered in Basel, Switzerland and with a history spanning of more than 150 years. It provides pharmaceutical solutions to patients and societies rising needs all over the world. Novartis' products are available in over 180 countries. In 2017, approximately 46 million patients benefited from company's healthcare access programs, while 15 million people around the world participated in health educational programs. The Novartis Group operates by employing more than 124,000 employees, of 145 nationalities at a global level.

Novartis Hellas

Novartis Hellas S.A., which is part of Novartis Group AG, is a dynamic company in the Greek pharmaceutical sector, while its development is founded on innovative treatments offered to Greek patients. Part of Group -as of 1 September 2017- is also Sandoz Greece, which will operate as an independent business unit of the legal entity Novartis Hellas in Maroussi, Attica. This means that Novartis Hellas is a multi-dimensional entity hosting both innovative pharmaceuticals departments (Pharma & Oncology), as well as generic parts and biomolecules (Sandoz). Main

Novartis Hellas business activities are focused on the area of prescribed medicines, which are available in the Greek market via a network of distributors and warehouses.

customers, who are served via the 198 available products, are the cooperating wholesalers, pharmacies and private clinics, as well as the State, via the public hospitals and the Primary National Health Network (PEDY).

The therapeutic categories are:

- Cardiovascular system and metabolism
- Central nervous system
- Ophthalmology
- Immunology, hepatology and dermatology
- Respiratory system
- Oncology, hematology and rare diseases

Basic financial results are:

FINANCIAL FIGURES (€)	2017	2016
Share Capital	23,60,692	23,360,692
Total (owners) Equity	138,831,354	135,357,697
Total Liabilities	61,477,277	57,459,413
Net Fixed Assets	4,691,805	4,761,354
Total Assets	200,308,631	192,817,111
Gross Profit	79,319,876	79,026,092
Net Profit before Taxes	8,882,750	13,395,765

Novartis Hellas, with a market share of approximately 9%, is the leading pharmaceutical company in Greece.

Supply Chain

We have approximately 1,500 suppliers across Greece and abroad, while the main categories are:

Product manufacturers (e.g. Famar)

· Co-promotion companies (e.g. Elpen, Pharmathen, WinMedica etc.)

TOTAL PURCHASE COST (2017)		Percentage of spending on local/Greek suppliers
Direct Purchases	€330 million	1%
Indirect Purchases	€27 million	95.7%

The Novartis Supplier Code includes the expectations we have from our suppliers, regarding fair labor practices, health and safety, environmental protection, animal protection, anti-corruption and data privacy.

Human Resources

Profile



Training and Development

The company implements many internal training programs, which gives us the opportunity to provide a large number of trainings with an emphasis on commercial roles.



Talent Development and Succession Plan

Novartis considers its people development and advancement as a top priority. Through institutionalized procedures (Organizational Talent Review, Talking Talent), talented employees who assume expanded tasks or higher positions are located and designated, thus ensuring both employees development and Novartis' meritocracy and success.

Rewards, Benefits and Additional Benefits

The Novartis Group strives to reward and provide benefits to employees, with an objective and balanced way, based on the Performance Management Program evaluation. It should be noted that Novartis Reward system is inextricably linked with each employee performance evaluation and country's overall results. The benefits are depicted in the following table.

Bonus	Private life and health insurance	Personal healthcare program
Annual Medical check-up	Private family insurance	Retirement plan
Child nursery allowance	Children feast	Marriage bonus
Child birth bonus	Parking spot	Company celebrations/events
Events invitations	Special prices for services and products	Car provision, gasoline and e-pass for employees' majority
Food provision at company's restaurant, for a full meal at a very low price and also free of charge provision for 3 smaller meals	Internet allowance for all employees	Business mobile phone for specific business roles

Development and Evaluation

Our company has as a priority to fill job openings internally, thus supporting employees' personal development plans, as well as the corporate succession plans.



Work Life Balance

- Holidays for Non Holidays: A day off is given when the employee has worked for a whole weekend
- Early Friday
- Flexible working hours: Employees have the opportunity to go to work between 08:00-10:00, depending on their personal obligations
- Work from home: Office employees have the opportunity to work from home up to 4 days per month
- Additional holidays
- "Be Healthy" activities and "Well-being" actions

During 2016-2017, 217 employees "worked from home" for a total of 2,743 days.

Equal Opportunities and Respect for Diversity

Leadership Team's Composition by gender and age group (%)

	<30 years old	30-50 years old	>50 years old
2017 Managers %			
Female	0	25.8	3.4
Male	0	19.5	1.5
2016 Managers %			
Female	0.4	27	2.6
Male	0	19.7	1.3

Environmental Responsibility

Environmental responsibility at Novartis Hellas focuses on four areas with strategic environmental impacts:

- energy and climate,
- water and micro-pollution,
- materials and waste, and
- environmental management (taking into consideration the precautionary principle).

Indicative Company's performance on the first 2 areas (energy and climate, water) is depicted below:



Participations and distinctions

Novartis Hellas participates in/is a member of:

- · Hellenic Association of Pharmaceutical Companies (SFEE) and Pharma Innovation Forum (PIF)
- Hellenic Advertising Association
- Hellenic Network for CSR
- · Corporate Responsibility Institute (CRI)
- Hellenic Management Association's Corporate Affairs Sector (TEYP)
- Hellenic Company for Pharmaceutical Management (EEFAM)
- American-Hellenic Chamber of Commerce
- In the Business Days program organized by the Strategic Business Administration and Entrepreneurship Research Center

Operational Excellence

FORTUNE'S WORLD'S MOST ADMIRED COMPANIES 2016

Novartis Hellas has again been included in the Fortune list with the "20 Most Admired Companies of Greece", which is one of the most important corporate reputation distinctions worldwide. The research was designed and implemented by KPMG and the Greek version of Fortune magazine. The companies were evaluated by more than 1,450 senior business executives based on 9 criteria, set by the American Fortune.

Corporate Responsibility

CR INDEX 2016 AND 2017

Novartis Hellas was distinguished by the Corporate Responsibility Institute, which awards companies with the highest Corporate Responsibility sense, according to the national CR INDEX. Novartis Hellas managed to win the gold award, demonstrating company's strategy that focuses on putting patients at the heart of its activities and on giving back to the society.

Working environment

BEST WORKPLACES 2016

Novartis Hellas won another important distinction by the international organization Great Place to Work, going up the 8th position among the first ten companies with the best working environment in the "over 251 employees" category. This distinction is the result of company's employees, which are the driving force and the most important company asset.

Message from the Head of Communications CORPORATE RESPONSIBILITY MANAGEMENT AT NOVARTIS HELLAS

Dear readers,

The concept of Corporate Responsibility has a different meaning for each and every one of us. For Novartis, this concept exceeds far beyond donations and charities being translated to creating value for the society. For this reason, Corporate Responsibility is integrated into our entire business operations and focuses on two pillars: expanding access to healthcare and doing business responsibly.

For Novartis, investing in research and development of new and innovative medicines is extremely important, as it endorses the right of every person to health. Over the years 2016-2017, Novartis Hellas implemented more than 100 clinical trials, involving more than 5,500 patients, 3 prevention and free examinations programs in 17 areas across the country, 5 awareness campaigns for important diseases in collaboration with scientific companies and patient associations. At the same time, we implemented 18 patient support programs for important diseases (oncological, neurological and rheumatological), we proceeded to drug donations and supported research projects in public hospitals, universities and scientific associations.

Regarding the creation of social value, at Novartis Hellas we have established the "Community Partnership Day", during which the approximately 500 Group employees dedicate, the company's founding anniversary, to people in need. Promoting volunteerism is among our priorities, so Novartis offers -throughout the year-opportunities for employees to make social contribution. Indeed, through the developed global Corporate Volunteering Platform, the possibility to work voluntarily in our country and abroad is given. At the same time, we supported the work of 19 NGOs and structures and contributed to the educational process upgrade by providing equipment in border line schools that suffer from infrastructure shortage.

Novartis Hellas, having placed patients at the core of its activities and remaining focused on its commitment to support them in practice, supported 34 patient associations. In cooperation with the Athens Medical Society, the "Right to Health" information campaign, a roadmap for patients' rights in our country, was launched in 2016, aiming at their unobstructed access to healthcare system. The initiative continued during 2017, focusing on clinical studies, with the aim of strengthening patient information and responding to any concerns.

Enhancing transparency helps shape a new culture that increases patient knowledge in relation to their rights and strengthens their trust relationship with healthcare professionals, academics and healthcare professionals, respective authorities and the pharmaceutical industry.

For Novartis, the Corporate Responsibility concept exceeds far beyond donations and charities and translates into creating value for the society.

Novartis Hellas corporate responsibility program was once again

acknowledged with a number of awards and distinctions, including the Corporate Responsibility Institute, where the company in 2017 won for the second consecutive year the Gold Award. Every time our efforts are rewarded, we feel satisfaction, but also responsibility to:

- Continue building trusted relationships with all our stakeholders and the Greek society that constitutes our home.
- Further strengthening the integrity culture in our organization and be fully transparent in our business operations.

Foteini Bampanara,

Head of Communications Novartis

Corporate Responsibility Strategy

At Novartis Hellas, we base our Corporate Responsibility approach on the following two areas:

DOING BUSINESS RESPONSIBLY

- Caring for employees
- Promoting business ethics and empowering governance
- Aiming for environmental protection

EXPANDING ACCESS TO HEALTHCARE

- Controlling and eliminating diseases
 - Pioneering in developing new
 business approaches and healthcare
 - Finding new treatments
 - Finding new treatments

Stakeholder engagement

Within the framework of our day-to-day operation, we interact with a dynamic group of stakeholders, with a variety and often conflicting needs and expectations, aiming to improve our patient-centric approach and more broadly, the responsible management of issues arising from the afore-mentioned dialogue. We recognize our stakeholders based on impact and influence they have on our company and vice versa. The basics stakeholder categories are:

- Academic and Scientific Community
- Healthcare professionals
- Patients and Caregivers
- Patient associations and other NGOs
- Media
- · Government, Regulatory and Business Healthcare Authorities
- Partners and Suppliers
- Novartis Group
- Employees

Materiality Analysis

Within the continuous improvement framework we adopt on corporate responsibility and sustainability issues at Novartis Hellas, during 2017, we proceeded with an electronic survey in order to prioritize those issues that have the most important economic, social and environmental impacts on stakeholders, as well as in their judgment and decisions respectively on Novartis Hellas. The methodology for the materiality analysis was based on the new GRI Sustainability Standards and on the three Principles of AA1000APS Standard. In particular, the analysis included the three below phases:

1. Issues identification 2. Issues prioritization 3. Validation



CATEGORY:

- ACCESS TO MEDICINES
- Lower-income patients
 Product pricing
- 3. Partnerships
- 4 Intellectual property
- 5. Non-communicable diseases (NCDs)

CATEGORY:

COMMUNITY ENGAGEMENT

- Direct economic value
 Society/community sur
- Society/community support programs
- 8. Cooperation with local/national suppliers
 9. Contribution in dealing with youth unemployment

CATEGORY: EMPLOYEES

- 10. Employees recruitment and retention
- 11. Enhancing diversity and inclusion 12. Occupational Health and safety
- 13. Fair working conditions, remuneration and benefits
- 14. Training and development

CATEGORY:

- ENVIRONMENT 15. Pollution, waste and effluents16. Energy and climate change
- 17. Green products and loyalty programs

CATEGORY:

- GOVERNANCE AND BUSINESS ETHICS 18. Integrity and compliance management 19. Responsible clinical trials

- 20. Bribery and corruption 21. Responsible marketing
- 22. Board structure and independence 23. Responsible lobbying
- 24. Risk and crisis management
- 25. Respect for human rights 26. Data privacy

CATEGORY:

- PATIENT FOCUS
- 27. Contribution to population's health
- 28. Demographic changes in society 29. Ensuring product offer/supply
- 30. Supply chain management and transparency

CATEGORY:

QUALITY OF DRUGS 31. Quality of drugs 32. Counterfeit medicines

CATEGORY:

- RESEARCH AND DEVELOPMENT
- 33. Research and Development innovation 34. Research and Development for rare diseases

CATEGORY:

- TRANSPARENCY AND COMMUNICATION
- 35. Stakeholder engagement and dialogue **36. Disclosure and labeling**
- 37. Prompt recalls/provide information in case

of problems 38. Public policy

39. Non-financial disclosure

Patient Focus

Why is it material?

Novartis, having set the patient at the center of its activities and inspired by giving priority to his or her needs, focuses on the research, development and sale of innovative high quality drugs. The company aims to improve patients' health and quality of life, ensuring they have access to its innovative treatments, while also contributing towards a sustainable health system. To this end, Novartis pursues co-operation with scientists and organizations from all over the world, setting at the same time high compliance and integrity standards. In parallel, for all of us at Novartis Hellas, Corporate Responsibility is an integral strategic element. It is integrated in our business operations, ensuring our sustainability, while it enhances our corporate reputation. Considering necessary employee contribution, we have innovated via the creation of the Interdepartmental Corporate Responsibility Team "Pharma". The Corporate Responsibility Team consists of 10 members, while all Novartis Hellas employees are welcome to take an active role in planning our CSR strategy, aiming to support the Greek patients and the wider society.

What is our approach?

Product supply security

Novartis' commitment on security of product supply concerns five key points, which are highlighted below.



Our target is to achieve 99.6% stock availability (to serve 99.6 from the 100 units ordered)

Health Outcome Contribution

Contributing to the health of the population is our core activity. We have as main focus areas the improvement of patients' health and quality of life, by providing services and products of holistic approach. Patients have additional benefits from the introduction and utilization of health technologies (medicines, devices, medical and surgical procedures). In the context of monitoring the cost-effectiveness of the Company's products in the healthcare system, Novartis Hellas is conducting specific pharma-economic studies to analyze the cost of the health system and the efficacy of each new drug based on clinical studies. Pharma-economic studies follow the principles of the health economics science and internal policies of the Company.

What is our performance?

Product supply security



Corporate Responsibility Actions

- COMMUNITY PARTNERSHIP DAY 2016

Using the message "From Human to Human", the Novartis Group employees participated actively in the "Community Partnership Day", which has become a tradition for the company. On Friday, May 20, more than 350 employees prepared first aid kits for refugees, which were handed over to the "Earth Organization – Center of the Earth" in collaboration with the "Pamperaiki Initiative for Refugees". Furthermore, Novartis employees cooked meals, which were then distributed to poor Greek families by NGO "Mporoume", which aims to reduce food waste, while fighting against malnutrition in our country. At the same time, Novartis employees in Thessaloniki visited the women's Orphanage "Melissa", where they carried out renovation work at their premises.

COMMUNITY PARTNERSHIP DAY 2017

The Community Partnership Day of Novartis Group took place in June 2017 in Athens and Thessaloniki, with the message "Moments of Love". More than 300 employees worked with enthusiasm, assembling furniture and games and preparing the meal of the day for the "SOS Greece Children's Villages", "Kallithea National Nursery School", "Smile of the Child" and "The Friends of the Child". The day's outcome was the assembling of 29 furniture and 95 games, while 200 meals portions were prepared.

• YOU ARE A WOMAN, YOU ARE POWER! in Athens, Thessaloniki and Patra

Novartis Hellas conducted a free-of-charge seminar program that focuses holistically on treating women patients. Thanks to the program "You are a woman. You are a Power! ", thousands of women suffering from breast cancer were given the opportunity to attend a series of free experiential seminars, aimed at their support and emotional empowerment. Novartis's goal was to put the woman in the center, by providing her with the necessary tools to help her discover her inner strength and persevere with resilience and determination. A total of 26 speakers presented, 105 hours of lessons were held and 3,307 people in total attended the seminars. The program was embraced by female patients, who described it as extraordinary, helpful, substantial, innovative and optimistic.

RIGHT TO HEALTH

Novartis Hellas, having placed the patient at the heart of its activities and remaining faithful towards its commitment to support them in practice, implemented the "Right to Health" campaign in co-operation with the Athens Medical Society. The campaign focused on informing patients about their rights, as well as in relation to clinical trials, with the aim of enhancing public awareness, responding to concerns, promoting transparency and strengthening the relationship of patients' trust with healthcare professionals, academics and healthcare providers, approval authorities and the pharmaceutical industry.

ANAPNEO (COPD CAMPAIGN)

The "Anapneo" campaign, an initiative of Novartis Hellas with the scientific support of the Hellenic Pulmonary Society (HPS), continued its journey to Greece inaccessible areas. The "Anapneo" campaign was designed by Novartis to raise public awareness about Chronic Obstructive Pulmonary Disease (COPD), while offering free spirometry to border areas residents, where access to qualified medical personnel and preventive exams, is difficult.

LIFE MEASUREMENTS

Focusing on Greek patient, Novartis has implemented the "Life measurements Program". The program was designed to help raise public awareness and inform citizens about the importance of preventing and regularly conducting diagnostic tests, through the provision of free primary care examinations. The program was organized under the auspices of the National Intermunicipal Healthy Cities Network - Health Promotion, the Hellenic Society of Hypertension, the Panhellenic Federation of Associations - Association of People with Diabetes and was held with the support of the local Municipalities and Medical Associations.

Corporate Responsibility Actions

Amount invested in grants, donations, sponsorships and social support programs
2017 → €2m
2016 → €3.4m

Research and Development

Why is it material?

Investing in Research and Development of new and innovative medicines is extremely important for Novartis. Our goal is to discover, develop and market innovative pharmaceutical products that prevent and cure diseases, relieve pain and improve quality of life. Research and Development, as well as the pipeline products are vital to the sustainability, future operation and long-term success of both Novartis Hellas and its subsidiaries Alcon and Sandoz.

What is our approach?

Innovation in Research and Development

We continuously invest in Research and Development on an international level, in order to discover and develop new therapies for treating hitherto unmet medical needs. Our Research and Development strategy focuses on therapeutic fields that represent our core strengths, such as the Cardiovascular System and Metabolism, Dermatology and Immunology, the Central Nervous System, the Respiratory System, Ophthalmology, Oncology, Hematology and Rare Diseases, as well as to explore additional areas that we believe to be ripe for innovation, like immuno-oncology, ageing and regenerative medicine.

Clinical trials in Greece

Even though €200 million is spent every year, Greece ranks poorly in pharmaceutical research, due to the existence of excessive bureaucratic red-tape. At the same time, countries in the enlarged EU, such as the Czech Republic, Romania and Hungary, make significant progress in this area.

Indicative benefits from clinical trials:

FOR THE NATIONAL ECONOMY → Influx of investment to Greece, job creation in health-related sectors and utilization of human resources in specialized sectors.

FOR THE NATIONAL HEALTH SYSTEM → Acquisition of scientific know-how, improvement of organization and equipment and significant revenues.

FOR THE PATIENTS \rightarrow Rapid access to new therapies, improvement of the therapeutic treatment for various diseases, more therapeutic options, increase in life expectancy, upgrading the quality of life, free research drugs and diagnostic/non-diagnostic tests.

FOR HEALTHCARE PROFESSIONALS \rightarrow New drugs, possibility of choosing the appropriate treatment, answers to scientific questions, knowledge expansion, experience increase, possibility of international recognition and continuous training in new therapies, methods and technologies.

Rare diseases

Our research priorities are not defined by the market's dynamic size. Rare diseases have historic barriers from the pharmaceutical companies, and many of them are still not understood. There are relatively few approved treatments for them and this is why we are fighting to expand the therapeutic portfolio used by doctors, thus helping the patients. We are focused in the field of rare diseases that cause serious impairment, where scientific understanding is strong and where we believe that new treatments could greatly improve patients' life.

What is our performance?

Novartis research programs are being evaluated -by qualified analysts- amongst the most dynamic of the pharmaceutical industry, focusing on strategically selected therapeutic areas and a wide range of unmet to date medical needs. In particular, internal audits and inspections are carried out by government bodies in Greece, in order to evaluate our performance. Based on the results of these controls, we are improving our respective approach.

Number of Internal Audits carried out globally by the parent company	Number of Inspections carried out by Greek and International governmental bodies
2017 $ ightarrow$ 5 audits (good outcome) 2016 $ ightarrow$ 2 audits (good outcome)	2017 \rightarrow 1 inspection (good outcome) 2016 \rightarrow 1 inspection (good outcome)

Novartis Hellas clinical trials investments

Number of clinical trials in Greece

 $\begin{array}{c} \textbf{2017} \rightarrow \textbf{93} \\ \textbf{2016} \rightarrow \textbf{114} \end{array}$

Total investment in clinical trials in Greece

2017 → €7.6m 2016 → €7m

Product Quality and Safety

Why is it material?

As an innovative global company in the health sector, Novartis commits to the development of an environment that sets as the utmost value the quality of products and services in order to fulfill the expectations of both patients and health authorities. Quality is not only related to the final product but is also of critical importance for all the activities that support the company's performance, ranging from discovering the molecule, to the development, production, supply and sale of the products.

Three pillars of quality strategy



What is our approach?

Drugs Quality

For Novartis Hellas, the drugs quality management is governed by the company's Quality Manual, which describes the Quality Management System and provides the quality specifications and expectations of the GxP. The Quality Manual applies to all Novartis Hellas' Departments and Business Units, in all locations, including the production and non-production units, from the development, to the commercial use and the product stewardship throughout their life-cycle.

Through the Quality Management System, Novartis Hellas:

- applies meticulous procedures for all products at all stages of production, based on specifications,
- investigates all deviations and defines the required corrective and preventive actions and maintains an organized system for recording, investigating and solving customer complaints,
- maintains a mechanism for managing recalls batches from the market, if necessary.

Prompt Recall/ Information in case of problems

Novartis has introduced a specific policy that describes the procedure, the responsibilities, the levels (consumers, suppliers, etc.) for the recall of a specific batch out of company's pharmaceutical products, in case this is considered necessary. The recalls occur for defective products or for products that do not fulfill all the approval requirements or are not able to fulfill the purposes they were intended for.

Disclosure and Labeling

Our products labeling requirements are determined on the one hand by the European and Greek legislative requirements, and on the other hand by the fundamental need for patients and health professionals detailed information. In accordance with the current legal authorities, we ensure that the information on the packaging of proprietary medicinal products is true and not misleading, while at the same time publishing any information about the medicine that is important for its safe and effective use. At Novartis, we are not just limited to apply existing legislation on product labeling, but we are further examining product labeling from a strategic point of view. We recognize that it is a crucial mechanism for maintaining compliance, enhancing our reputation and branding, improving operational efficiency, developing the Company, but above all protecting patients.

What is our performance?

Drugs Quality

At Novartis we ensure quality governance and quality design at country level through the:

- · Implementation of quality systems and procedures,
- Implementation of the annual Quality Plan,
- Annual Quality Management Report (AQMR),
- Quality Committees,
- Appropriate Key Quality Indicators (KQIs), and
- Quality Risk Assessments.

Novartis Hellas regularly monitors the relevant statutory, regulatory and legislative frameworks in order to fully comply with them. The result of this practice is that for 2016 and 2017, there were no incidents of non-compliance with laws of regulations, regarding the products' impacts, the information the company provides and the labelling its products have to follow.

Confirmed complaints submitted to the Department of Quality Assurance

 $\begin{array}{c} \textbf{2017} \rightarrow \textbf{68} \\ \textbf{2016} \rightarrow \textbf{69} \end{array}$



Prompt Recall/Information in case of problems

During 2016-2017 there was no recall incident, in addition to the virtual recall that takes place annually for precautionary purposes and which ensures the organization's readiness in case of need.

Disclosure and Labeling

During 2016-2017, there were no regulatory incidents of non-compliance with laws and regulations, regarding the information provided by the company and the labels that should accompany its products.

Governance and Ethical Business Practices

What is our approach?

In response to the latest developments and public debate on our business practices, Novartis Hellas collaborates with the Greek and U.S. authorities to investigate the case with a sense of responsibility and integrity. We commit ourselves to taking all necessary action, in case practices that do not comply with ethical business standards are established. Along with the investigation process, we continue to stand by Greek patients and their caregivers, health professionals and the Greek society. Since 2015, Novartis continues to take global initiatives to enhance the integrity that distinguishes the company, in order to respond to the ever-increasing and changing society expectations for responsible business, especially by global health companies, integrating high ethical standards into our organization. More specifically, in order to cope with these expectations, which often exceed regulatory requirements, we conducted a series of multiannual initiatives, fully in line with our values.

Corporate Governance

Novartis Hellas' Corporate Governance System aims to ensure the company's transparent, sound and effective management, contributing substantially to its long-term sustainability. For this reason, the company follows responsible internal operations and Corporate Governance practices, based on international standards. The company's governance team is illustrated in the following organizational structure:



Integrity and compliance

Our mission: Our mission is to help people live more and with better quality of life. With respect to our mission, we are committed to timely and uninterrupted access to our treatments. Patients who take our medications will not be left without the necessary for them treatment. We are constantly aiming to create value for each stakeholder, by encouraging those who have invested money, time and ideas in our Company.

Our Vision: Our vision is to be a trusted leader in changing the practice of medicine.

Our Values: Strong values define our culture and help us execute the Novartis strategy in line with our mission and vision.



Regulatory Framework

The company abides by the statutory codes of conduct in all of its research activities and operational practices, while it takes measures that reduce the possibility of corruption incidents, through the Policy Framework that includes:

- Corporate operational issues (e.g. Code of Conduct)
- · Product issues (e.g. Policy NP4- Novartis Pharma Principles and Practices for Professionals)
- · Anti-Bribery Policy, Conflict of Interest Policy

Internal Code of Conduct

Novartis Hellas has developed and adopted -since 2012- a Code of Conduct that reflects company's commitments towards its stakeholders while it includes basic principles and rules for ethical business behavior. During 2016-2017, the Internal Code of Conduct was revised and strengthened in order to include the following:

- Prohibition on providing gadget to health professionals.
- Prohibition of any cultural recognition to health professionals.
- · Supporting health professionals at international conferences, only in exceptional cases.
- · Promotional consultations with speakers under restrictions.

Novartis Code of Conduct is an integral part of employment terms of all Novartis Group employees and for this reason the company trains both its new partners and all its staff with regard to the Code of Conduct and its individual principles. At the same time, a process of reporting and managing related professional misconduct has been instituted.

Bribery and Corruption

Enhancing our compliance program with anti-bribery is a key element of our vision to become credible leaders in the industry. Furthermore, Novartis' anti-corruption policy was revised and enhanced in July 2016 and then in May 2017. The key points enhanced/renewed and included in the policy are presented in the graph below:



Responsible Marketing

Novartis has developed and implements the Novartis Pharma Principles and Practices for Professionals policy (NP4), which sets out Novartis' minimum requirements worldwide with regards to the most common practices related to promotional and non-promotional activities. In addition, any practice must comply with all applicable laws, regulations and codes governing the pharmaceutical industry, as well as local NP4 policy standards, which may often impose stricter requirements. NP4 Policy addresses the following principles:

- Independence of Health Professionals
- Purpose of collaboration with Health Professionals
- Differentiation between promotional and non-promotional activity
- · Promotional content

- · Non-promotion before approval and non-promotion of off-label
- · Reporting of adverse activities
- Patients' data protection

Responsible Clinical Trials

We recognize that the clinical trials outcomes should be used to promote public health and we are committed to provide access to information on clinical trials to everyone, including the results of these trials, positive or negative. We commit to publish the results, after clinical trial completion. When clinical trials are completed successfully, we register our new drugs in each country in which patients participated in trials. When a drug is registered and is not commercially available, we are committed to providing it, in accordance with each country laws, to patients who participated in trials, to ensure their treatment is not interrupted.

Data privacy

Novartis Hellas complies with all data privacy laws and implements clear policies for the protection of personal data, including genetic data. We strongly condemn the disclosure of any information that could lead to any form of discrimination, as well as the use of identifiable genetic data without consent. Novartis Hellas also follows relevant Binding Corporate Rules (BCR), in addition to the Company's Standard Operating Procedure on personal data privacy issues, which includes, among other things, the Legal Department's information on any activity involving the processing of personal data. BCR aims to ensure an adequate protection level in the personal data processing and transfer of Novartis employees, patients, clients and other partners, suppliers and business partners, as well as data of people involved in research and pharmacovigilance.

What is our performance?

Bribery and Corruption

Novartis' Hellas anti-corruption policies and procedures have been notified to all 5 BoD members (100%), to all (100%) company employees in Athens and Thessaloniki and to all (100%) of Novartis Hellas' major business partners in Greece. All (5) Novartis Hellas' BoD members (100%) have received training related to anti-corruption.

TRAINING ON COMPLIANCE & ANTI-CORRUPTION ISSUES 2017		
Training topic	Number of employees who were invited to take the training	Percentage of employees who completed the training
Integrity and Compliance for new recruits – internal partners	477	94%
Integrity and Compliance for new recruits – external partners	477	100%
Adverse Incidents Reporting	477	98%
Code of Conduct	477	99%
Data privacy	477	98%
Anti-bribery	477	97%
Information management	477	97%
Professional practices policies – Ethical business practices	477	99%

Responsible Marketing

During 2016-2017, there were no incidents of non-compliance with the regulations or voluntary codes on marketing communications, including advertising, promotion and sponsorship.

Responsible Clinical Trials

During 2016-2017, there were no incidents of violation of the privacy of volunteers and patients, participating in clinical trials or personal data loss events.