



**DEMO S.A.**  
PHARMACEUTICAL INDUSTRY

# SUSTAINABILITY REPORT 2018







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### COMPANY PROFILE

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## Top quality in injectable products

Fifty three years ago, we committed to the development and expansion of our activities with only one goal: to offer the best possible choices in the pharmaceutical industry.

The vision and our strategy focus on the development and production of pharmaceutical products of high quality at competitive prices, promotion of innovative products for the relief of chronic diseases and exports at a global level.

## International Presence

DEMO S.A. has established a dedicated team within our International Sales Division that is charged with participating in **the biggest tenders worldwide** – including those organized by the World Health Organization, the International Committee of the Red Cross, Ministries of Health & statewide agencies located in all five continents.



“Find what  
you are good at  
and try to be  
the best”

**Dimitris Demos**

General Manager of DEMO S.A.

Our steady development from a simple drug store in 1965 to one of the greatest pharmaceutical industries all over the world in the production of injectables is no luck but it is a result of our methodical efforts for years and a series of strategic choices.

**In numbers, it is characteristic that, despite the great blow that the drug sector suffered in the decade 2008 - 2018, the company has invested more than 60 million euros, it has almost doubled its turnover, making an increase of 42% (from 90 million euros in 2008 to 138 million euros in 2018), while additionally it has over-doubled its sales abroad.**

As regards the investment plan of our company, in 2018 it completed 90%, even a very difficult project, such as the creation of a new unit for the production and packaging of glass ampoules of a total capacity of 150 million ampoules (from 25 millions that was the capacity until today). This project was executed at a record time with very impressive results.

Expectations for the further development of DEMO in 2019 are great and they are based on the whole infrastructure, investments and the work that was done in the previous years. We are expanding our already expanded hospital portfolio, by developing an important number of new injectable pharmaceutical products. We are enhancing our presence in the out-of-hospital market with new orally administered treatments, while we are expanding also to the dietary supplements and medicinal equipment category, by selecting high-standard and clinically certified preparations. Nonetheless, one of the most important objectives is to further expand our portfolio of products by adding mainly biosimilar or other biomedical products which are intended for serious and chronic diseases. These products are the capstone of exclusive collaborations of DEMO with important pharmaceutical companies in Europe and USA for their distribution in the Greek market.

Finally, DEMO is a cooperation that expands quickly by creating many new working positions. At this moment, we have adequately trained and educated our staff of 920 people, while during the financial crisis instead of firing people and decreasing their compensations, we keep hiring remarkable people and maintain the level our wages steady. According to our projections and also based on the business plan that we will follow, 200-300 additional working positions shall be created in the next 4 years.

Of course this happened because long before the crisis we chose to target foreign markets and we made great investments in order to meet this strategic goal. Our factory is the greatest in Southeastern Europe, and at the same time our additional investments allowed us to dominate domestic hospital market, where we have been having for years the leading position.

**Stavros Demos**  
Chairman of DEMO S.A.

# 01



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# DEMO S.A.

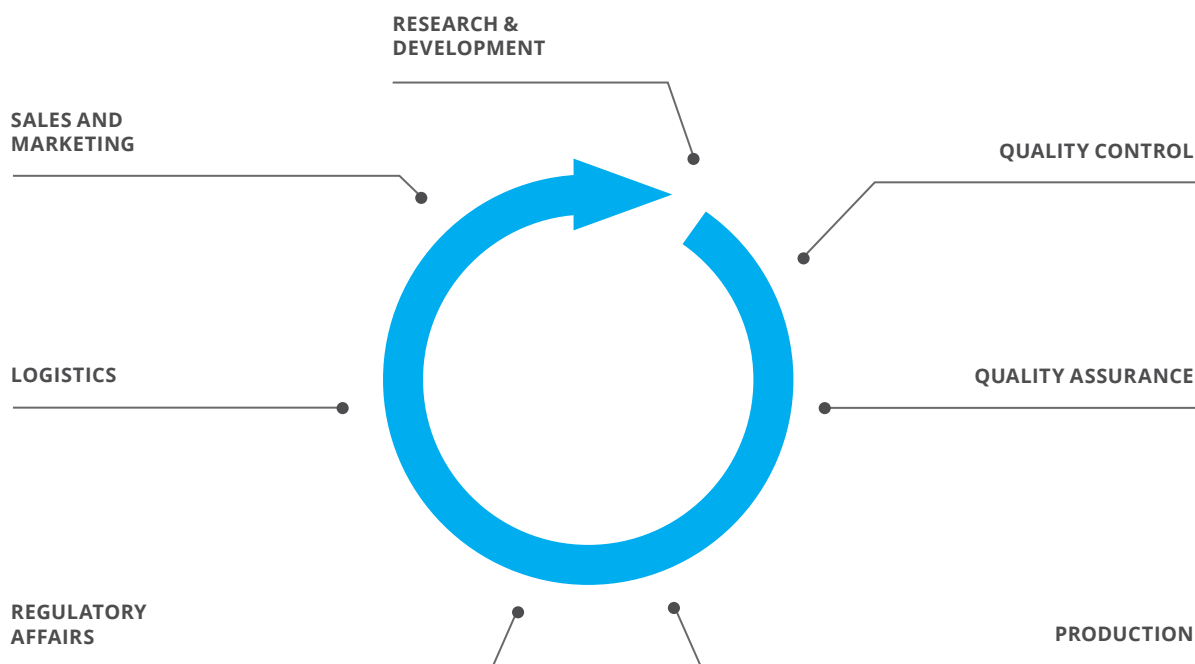
DEMO S.A. Pharmaceutical Industry is an industrial and commercial organization, active in the development, production and sales of pharmaceutical products.

The company's manufacturing plant in Kryoneri of Attica, is the largest in Southeastern Europe and one of the world's largest, with state of the art facilities of 57,000 m<sup>2</sup>, including and a very hi- tech Quality Control Laboratory of 1,600 m<sup>2</sup>. DEMO S.A. is one of the major pharmaceutical manufacturers in Greece with a very strong presence in the hospital market, ranking first among all the Greek pharmaceutical companies in terms of units sold. The company's product portfolio includes many injectable generic pharmaceutical formulations from several therapeutic categories including: Injectable products of all forms such as Liquid injectables in glass ampoules, vials & bottles, sterile powders and freeze – dried formulations, Lyophilised products, Emulsions, Penems, Penicillins, Cephalosporins, Urology).

DEMO has faithfully served its export orientation over the last years, with its sales network expanding to Europe, Asia, Africa, the Middle East, South America and Oceania. The company exports 81% of its annual production and is rapidly expanding its range of products to international markets along with timely and safe delivery. It is internationally recognized as one of the official suppliers of the United Nations, UNICEF, World Health Organization, MSF and the International Red Cross. With 2.000 presentations in 85 countries worldwide and 920 staff, DEMO aims to reliably meet the needs of the market in Greece and internationally.

Our cutting edge production facilities allow us to offer our partners services such as:

- Worldwide distribution opportunities
- Out-licensing services
- Contract manufacturing operations.



**No 1**Hospital Sales in Greece  
(in terms of units sold)**No 1**Exporter of Pharmaceutical Products  
(in terms of own branded units sold)**No 1**The biggest manufacturing facility  
for injectables in Greece and  
one of the biggest in Europe

## Vision

DEMO S.A. is committed to long-term growth, both in Greece and globally.

Our vision is to consistently be one of the best companies in the pharmaceutical market, maintaining our leading position in the Greek Pharma industry, positive growth rate and the preference of our customers and partners based on their trust in our products and our company.



**Greek Medicines  
with  
Global Reach**

## Mission

**DEMO intends to maintain its leading position in the Greek pharmaceutical industry while further establishing its role as one of the top manufacturing companies worldwide.**

Having already achieved rapid growth in the global generics pharmaceutical market, we aim to contribute with innovative, quality products and services, improving the lives of patients worldwide and ensuring the steady confidence of our customers. Our modern and fully equipped manufacturing premises, the advanced technologies that we have adopted, our constant product portfolio expansion and our international presence are the means to the end.

Therefore, we have invested heavily in the creation and sourcing of our state-of-the-art Research & Development laboratory. DEMO's R&D lab spans more than, 1.600 m<sup>2</sup> is equipped with the latest instruments and is staffed with the top graduates of the University of Athens. Under the supervision of highly qualified researchers – most of who own PhD degrees from the most acclaimed universities in Europe – our R&D lab represents the company's launching pad for the future!

# DEMO SA core values are the guiding principles that dictate our Behavior & Actions

## Flexibility

- Drive Change Actively
- Leverage our knowledge to adapt our strategy to every market
- Work closely with the customers

## Efficiency

- Access profitability
- Manage resources in a smart way
- Ensure sustainable business development

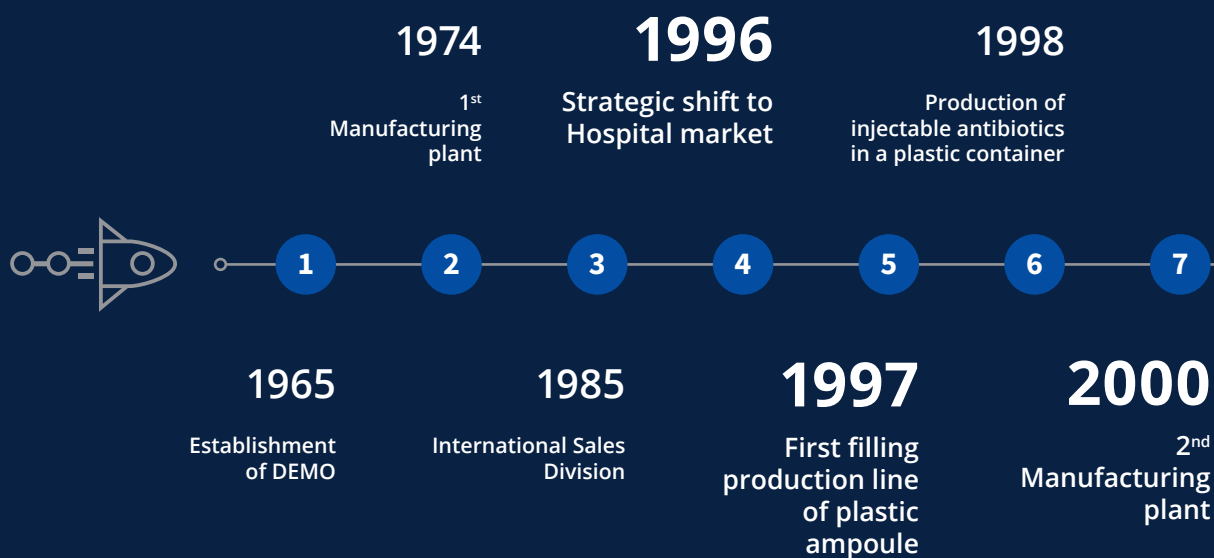
## Responsibility

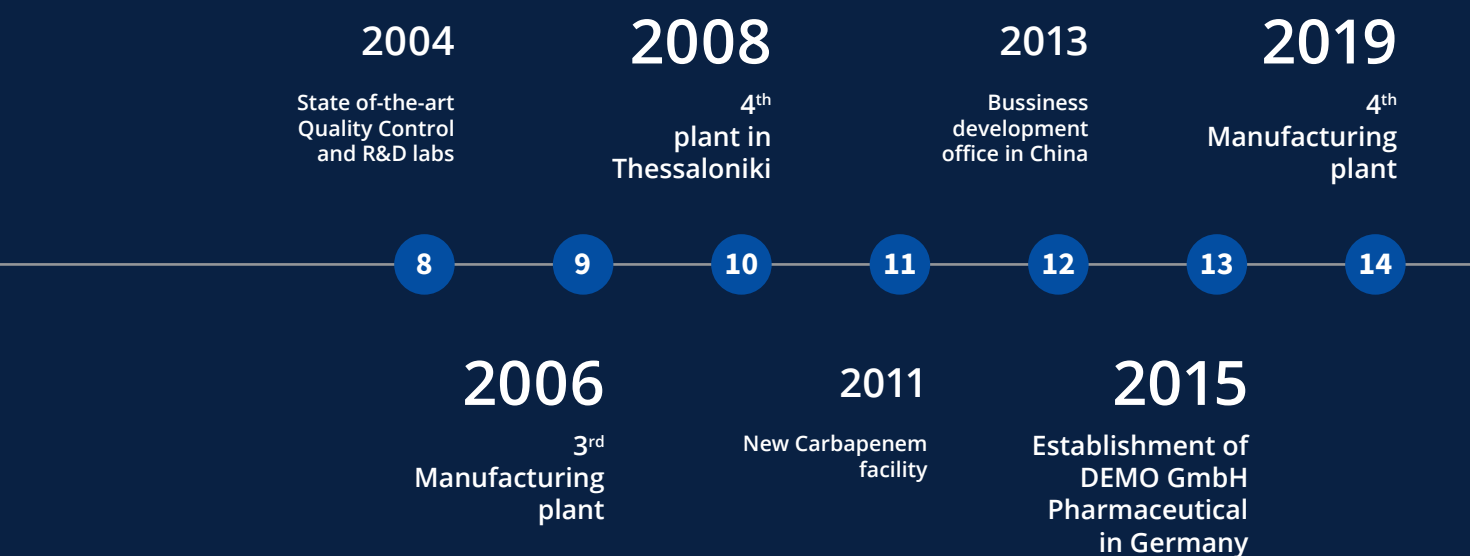
- Think and Act with patients in mind
- Transparency & ethical marketing
- Safety and quality are paramount

## Trust

- Treat each other like family
- Be honest, do not compromise the truth
- Build long lasting relationships with our partners

# More than **50 years** of dynamic presence in Greece and worldwide







# Global Presence

## We successfully export in 85 countries

The company's International Sales Division has a long history of successful participation in international tenders procured by the most accredited organizations worldwide.

Hence, DEMO S.A. has established a dedicated team within our International Sales Division that is charged with **participating in the biggest tenders worldwide** – including those organized by the World Health Organization, the International Committee of the Red Cross, Ministries of Health & statewide agencies located in all five continents.

## Official Supplier of the United Nations & UNICEF

Our company sees its successes in more than just financial and operational terms. This is the reason we decided to become a registered supplier for numerous international aid organizations, including both **UNICEF, MSF and United Nations.**

We feel honored to be a selected partner of these two organizations and be able to provide them with all the help needed to succeed in their mission.

In 2007, the **United Nations Relief and Works Agency and Welfare Agency (UNRWA)** designated DEMO as one of its top suppliers, hence strengthening the company's reputation as a leading, truly international pharmaceutical manufacturer.

## Logistics Expertise

Our company's International Sales Division partners with the biggest logistics companies worldwide to offer its products at any place in the globe.

An extended network of affiliated agents allows DEMO to provide best-in-class customer service regardless of the territory in which our partners reside.

# 81%

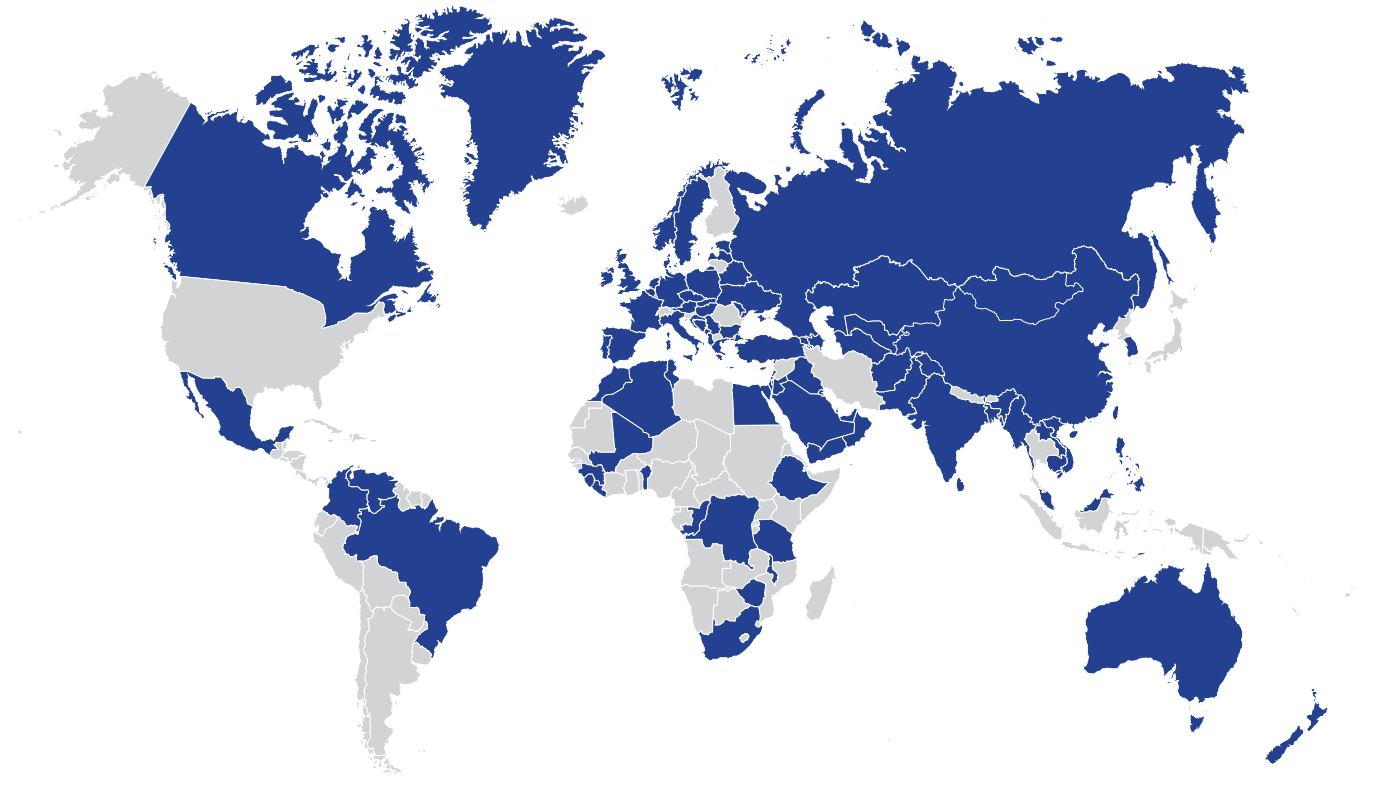
of the company's annual production is exported to international markets



## Our success is based on our unique combination of strategic advantages:

- Investment in large scale production capacity via state of the art technology
- Rapid expansion of our product portfolio.
- Continuous & careful investment in human resources.
- Open, honest & timely communication with our partners worldwide.
- On-time distribution and product delivery.
- Immediate supply of any urgent needs in pharmaceutical.
- A clearly defined corporate philosophy based on the principles of quality, growth, professional & flexible management.
- Financially solid company.





### DEMO S.A. Products

(including pending submissions & rest of the countries which are reached via CMO agreements)

**2013:** Moldova, Sierra Leone, Syria, Spain, Vietnam



**2014:** Bahrain, Italy, Liberia, Malawi, Sri Lanka, United Arab Emirates, Zimbabwe



**2015:** Afghanistan, Australia, Bangladesh, Benin, Cambodia, Croatia, Democratic Republic of the Congo, Gambia, Guinea, Kingdom of Saudi Arabia, Laos, Maldives, Mali, Mongolia, East Timor, Ukraine



**2016:** Myanmar, Tasmania



**2017:** Algeria, Czech Republic, Hungary, Slovenia, Oman



**New countries 2018:** France, Sweden, Denmark



## Internationally Recognized

### Officially Approved Supplier of:

- United Nations
- UNICEF
- World Health Organization
- Medicines Sans Frontiers
- International Committee of the Red Cross

### Approved by:

- PIC/s countries (Europe, Switzerland, Australia, South-East Asia, Canada)
- Korean-FDA
- Brazilian Drug Agency (ANVISA)
- GCC (Health Minister's Council for Cooperation Council States) – Gulf countries

- Many other health authorities of non-EU countries (Jordan, South Africa MCC, Egypt, Turkey, etc.)



COUNTRIES	APPROVED	UNDER APPROVAL	TOTAL
ALBANIA	44	0	44
ALGERIA	0	1	1
AUSTRIA	78	19	97
AUSTRALIA	7	0	7
AZERBAIJAN	13	0	13
BAHRAIN	3	7	10
BELARUS	1	0	1
BELGIUM	27	25	52
BOSNIA-HERZEGOVINA	4	0	4
BULGARIA	6	0	6
CHINA	1	0	1
CROATIA	1	0	1
CYPRUS	170	36	206
CZECH REPUBLIC	8	5	13
DENMARK	30	3	33
ESTONIA	3	0	3
ETHIOPIA	10	3	13
FRANCE	37	23	60
GERMANY	127	16	143
GEORGIA	9	1	10
GREECE	801	95	896
HONG KONG	12	0	12
HUNGARY	3	4	7
ICELAND	0	17	17
IRAQ	10	11	21
IRELAND	46	21	67
ISRAEL	2	1	3
ITALY	2	23	25
JORDAN	66	9	75
KAZAKHSTAN	10	0	10
KOREA	4	0	4
KOSOVO	21	0	21
KURDISTAN	1	0	1
KUWAIT	3	3	6
KYRGYZSTAN	7	2	9
LEBANON	7	16	23
LUXEMBOURG	8	32	40

DATA 30.06.2019

COUNTRIES	APPROVED	UNDER APPROVAL	TOTAL
MALAYSIA	16	0	16
MALDIVES	1	0	1
MALTA	25	0	25
MEXICO	2	0	2
MOLDOVA	6	1	7
MONTENEGRO	0	13	13
MOROCCO	2	1	3
NETHERLANDS	15	24	39
NEW ZEALAND	28	4	32
NORWAY	11	0	11
OMAN	7	3	10
PAKISTAN	2	0	2
PALESTINE	1	0	1
PHILIPPINES	5	0	5
POLAND	12	11	23
PORTUGAL	86	53	139
QATAR	1	0	1
SOUTH AFRICA	17	14	31
SERBIA	1	16	17
SLOVAKIA	6	5	11
SLOVENIA	0	1	1
SPAIN	43	4	47
SRI LANKA	1	0	1
SUDAN	11	6	17
SYRIA	0	2	2
SWEDEN	27	6	33
TAJIKISTAN	8	0	8
TUNISIA	4	0	4
TURKEY	20	6	26
TURKMENISTAN	5	1	6
UNITED ARAB EMIRATES	0	9	9
UKRAINE	6	4	10
UNITED KINGDOM	102	24	126
UZBEKISTAN	8	1	9
VIETNAM	27	11	38
YEMEN	13	10	23
ZAMBIA	0	10	10

**2.101**  
APPROVED

**613**  
UNDER APPROVAL

**2.714**  
TOTAL

# Our Facilities

## Attica

The first manufacturing plant in Greece filling injectables in plastic ampoules. The largest pharmaceutical factory of Southeastern Europe with a global reach.

Our headquarters are located in the industrial zone of Athens and specifically in the northern suburbs. Our four manufacturing plants spanning 57,000 m<sup>2</sup> are located in the company's campus facilities in Athens.

This fact, along with high tech warehousing in both Athens and Thessaloniki provide our company with the ability to offer our own logistic services to all hospitals countrywide.

In addition to facilities in Attica, the company maintains offices and Logistic Center in Thessaloniki 5.748 m<sup>2</sup>, a subsidiary company in Germany (DEMO GmbH) and offices in China.

**57.000**  
m<sup>2</sup>

Facilities

**4**

Manufacturing  
Sub-Units

**25**

Production  
Lines

**33**

Packaging Lines





## 4<sup>th</sup> Manufacturing plant

(building on the left)



# Location and premises

## Company's premises

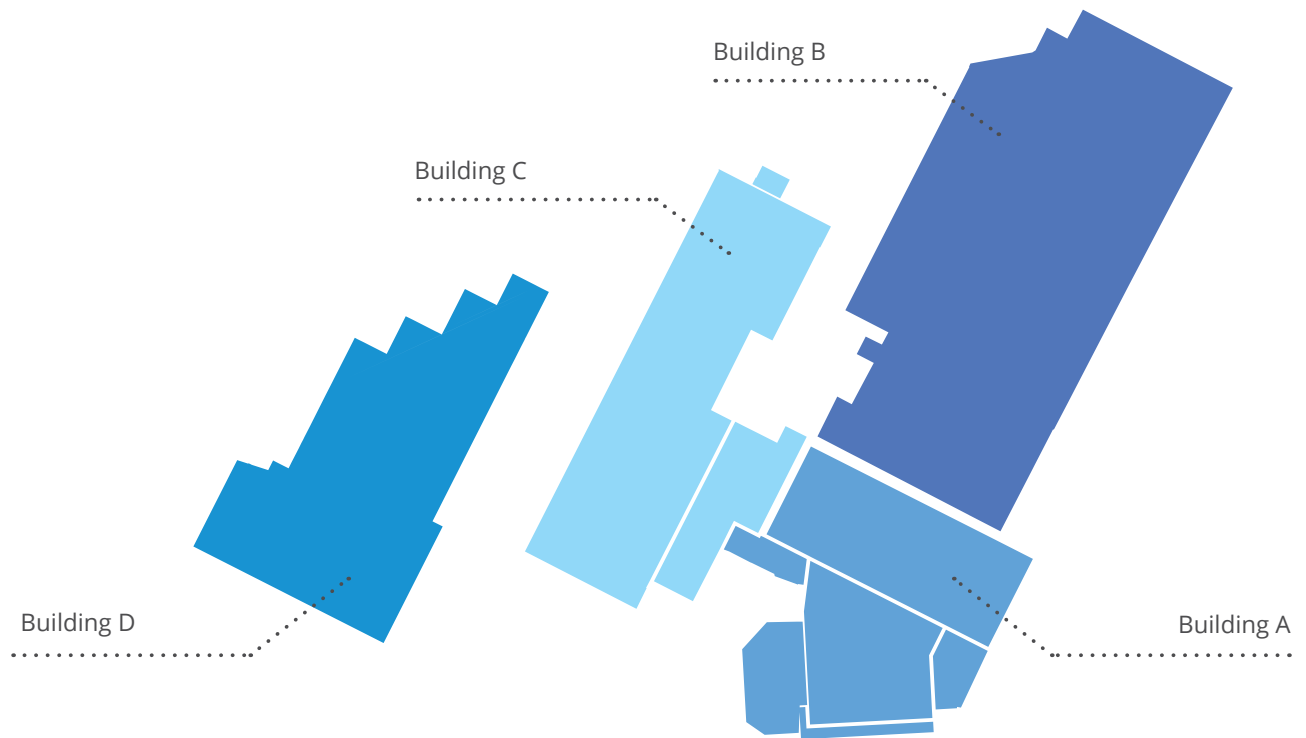
The Company's headquarters are situated in the industrial zone of Athens, in the northern suburbs of Attica region. Moreover, there are office and warehouse premises in Thessaloniki (2nd largest city, in northern Greece).

Headquarters in Athens extend to an area of 57,000 m<sup>2</sup> approximately and comprise of three buildings that accommodate the Company's production, quality control and R&D facilities, warehouse and office buildings. The area in m<sup>2</sup> per building and facility is presented in the table in m<sup>2</sup>. Athens premises (buildings and machinery) are covered by insurance contact with HDI-Gerling, expiring in April 2017.

The Company's premises in Thessaloniki extend to a total area of 5,750 m<sup>2</sup>, approximately. Warehousing of pharmaceuticals extends to 1,429 m<sup>2</sup>. There is extra office and warehousing area of 1,432 m<sup>2</sup>, as well as 2,887 m<sup>2</sup> free and available for future use.

Area (sq.m) per type of use in Athens premises					
TYPE OF SPACE	BUILDING A	BUILDING B	BUILDING C	BUILDING D	ALL BUILDINGS TOTAL
Warehouses	3.300	5.000	8.500	12.000	28.800
Quality Assurance	220				220
Quality Control	720		200		920
R&D	550				550
Regulatory Affairs	200				200
Technical Areas	410	2.000	1.400		3.810
Technical Services		1.000			1.000
Offices & Common Areas	3.800	1.500	1.500		6.800
Production & Packaging	800	10.500	2.800		14.100
Total sq.m	10.000	20.000	14.400	12.000	56.400

## Athens building



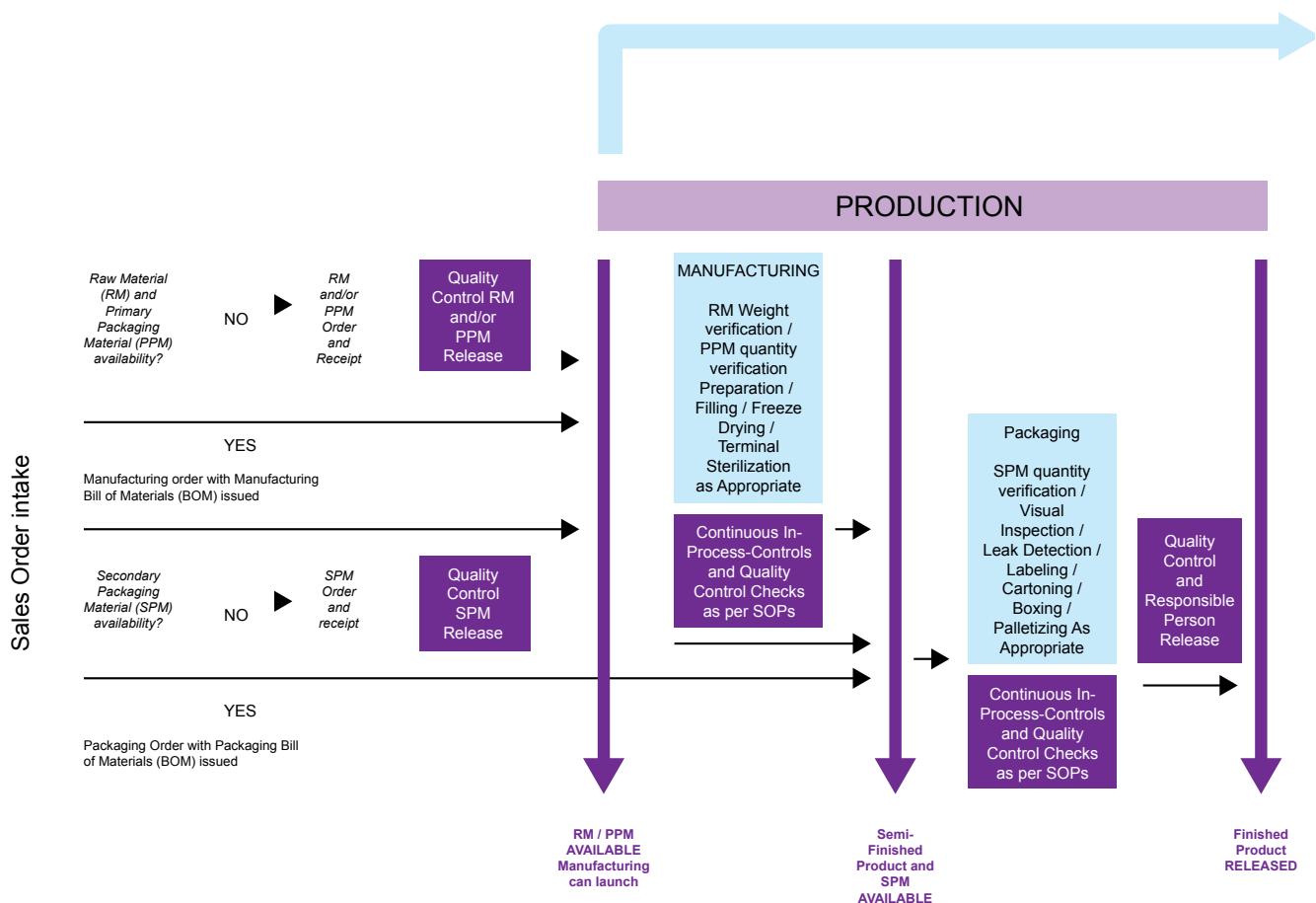
Area (sq.m) per type of use in Thessaloniki premises		
TYPE OF SPACE	FLOOR	AREA
Warehouses	Basement	1,429
Reception, office space, warehouses	Ground floor	1,432
Free space	1 <sup>st</sup> Floor	1,444
Free space	2 <sup>nd</sup> Floor	1,443
Total sq.m.		5,748

Area (m <sup>2</sup> ) of Buiding D	
Warehouse I	2.721,11 m <sup>2</sup>
Warehouse II	2.421.84 m <sup>2</sup>
Total sq.m	5.142,95 m <sup>2</sup>
1 <sup>st</sup> Floor	1.801,77 m <sup>2</sup>
2 <sup>nd</sup> Floor	1.674,30 m <sup>2</sup>
3 <sup>d</sup> Floor	1.640,83 m <sup>2</sup>
Total sq.m	10.259,85 m <sup>2</sup>

# Appendix: Product Manufacturing Flowchart

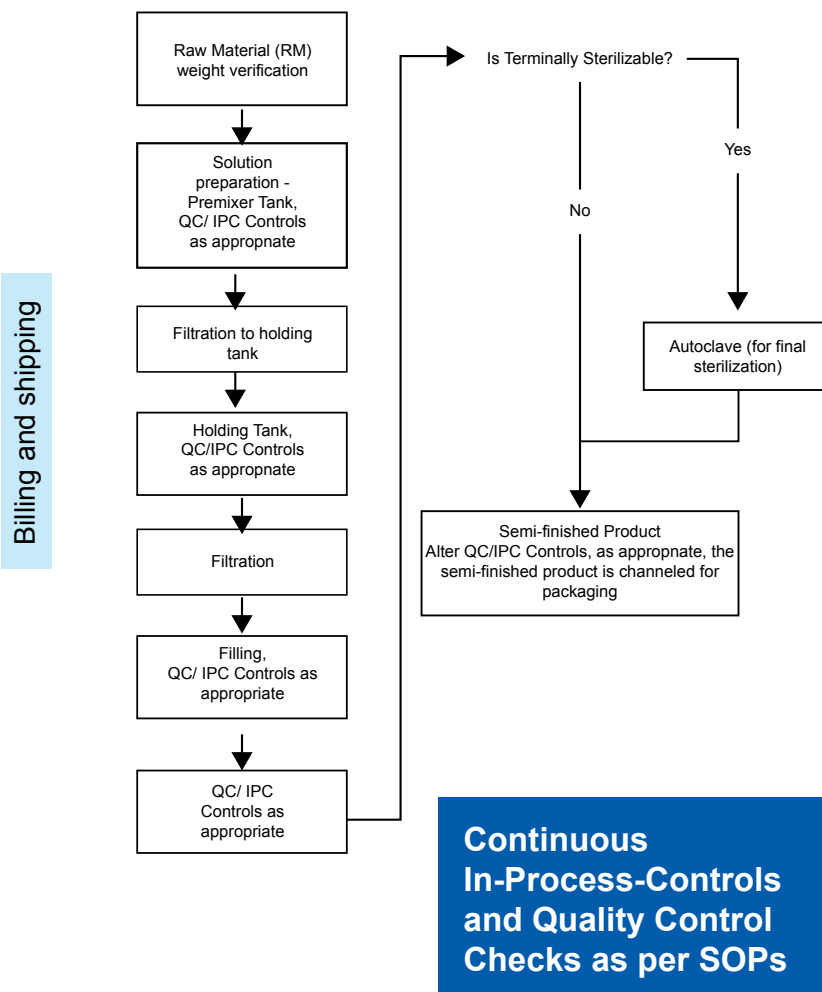
## Production Flowchart for liquid injectable manufacturing

Presented below is an overall production flowchart, as well as flowchart for aseptic and terminally sterilized products preparation.





### Aseptic preparation and terminal sterilization





# Investments

# Growth

It is characteristic that at the governmental operational plan entitled “Greece: Strategy for future development” that was communicated in the summer of 2018 to the European institutions, one of the main development sectors are considered to be transportation and supply chain, energy, agro-food, processing, marine, drug industry, **health** and environmental economy, tourism and civilization.

**IOBE** also proceeded to the estimation of the financial **drug footprint to the Greek economy**. According to estimations, the total contribution of the medicinal sector in the GDP is about €6.1 billion (3.4% of GDP) in 2017. So, for €1 added value of the companies in the medicinal sector, €2.9 more are created for the Greek economy in total. Finally, the impact in tax income from the activities in the medicinal industry is expected to be approximately €1.7 billion.

Modern Greek drug industry has **27 production units using state-of-the-art technology** and sophisticated quality control systems and it is specialized in the development and production of generic medicines and pharmacotechnical innovation products with high added value. Every year it offers more than 30 million euros in investment and research programs. 11,000 employees and 800 highly-specialized scientists are working in this field while it affects 53,000 working positions directly or indirectly.

**DEMO S.A. invested more than 60 million euro, and it has almost doubled its turnover, making an increase of 42% (from 90 million euros in 2008 to 138 million euro in 2018), while at the same time it has over-doubled its sales abroad.**



DEMO's investment plan is still in progress and it is expected to be completed by mid 2019. In particular, we have upgraded and extended all our production lines aiming at multiplying our capacity. **Practically we are expecting to triple our producing capacity within one year.**

**In numbers, this means that in the last 10 years the company invested more than 60 million euros (out of which 20 million the last three years) in its production facilities, both in order to increase its production capacity and also to automatize its production procedures and controls during production.** In 2017 the construction of the 4th unit of the company started, which is now completed, and it helped significantly the warehouses expansion. Finally, out of **€60 million, €10 million were invested in the research and development of new products.**

Within this framework, the company expanded its already expanded hospital portfolio, by developing an important number of new injectable pharmaceutical products. Furthermore, it enhanced its presence in the out-of-hospital market with new orally administered treatments in various therapeutic categories, while it is expanding also to the dietary supplements and medicinal equipment category.

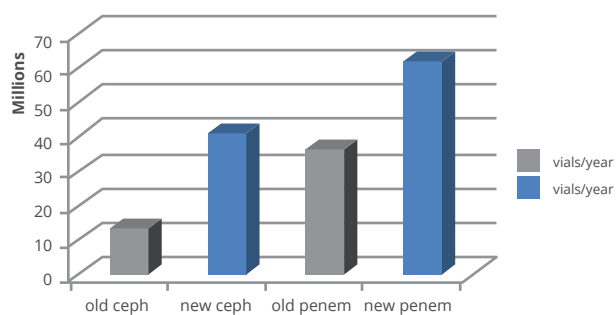
In 2019, the most important project that started is the new production unit of glass bottles and lyophilised products at a capacity of 150 million bottles in a liquid form and 20 million bottles in lyophilised format. It is an investment that shall make DEMO one of the 3 greatest lyophilised product producers in Europe and it is a part of the company's new investment plan for the years 2019-2022, in total 30 million Euro.

# Investments

## Growth

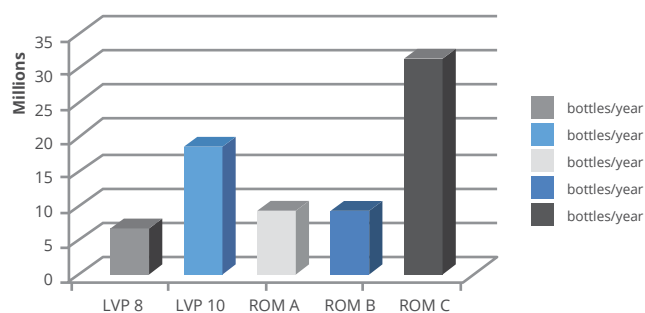
Old machines VS new one  
(Cephalosporin / Penem)

vials/year



Bottles/production capability per year

bottles/year

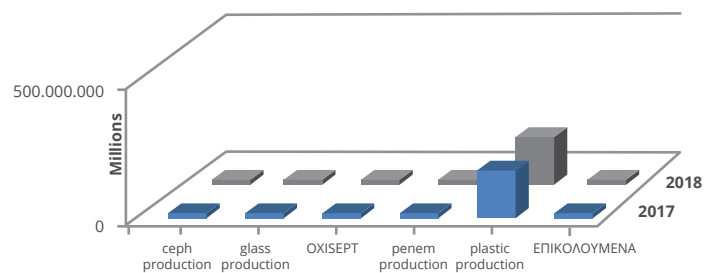


CEPH	viasl/min	vials/hour	vials/day	vials/year
Old	26	1560	37.440	13.665.600
New	70	4200	100.800	36.792.000
PENEM	viasl/min	vials/hour	vials/day	vials/year
Old	50	3000	72.000	26.280.000
New	240	14.400	345.600	126.144.000

BOTTLES	bottles/day	bottles/year
Old	115.920	42.310.800
New	202.320	73.846.800

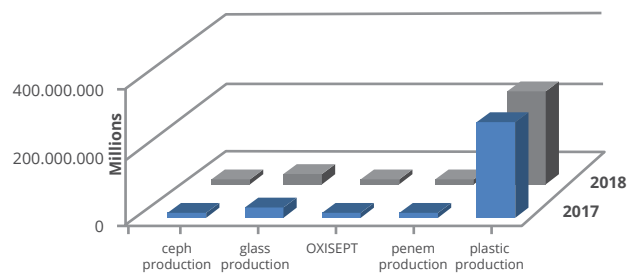


Final products 2017 vs 2018 (pieces)



	ceph production	glass production	OXISEPT	penem production	plastic production	ΕΠΙΚΟΛΟΥΜΕΝΑ
2017	3.207.911	12.372.645	239.449	5.392.425	197.272.559	677.889
2018	4.445.292	15.787.834	184.207	5.324.037	215.313.911	706.682

Semi products 2017 vs 2018 (pieces)



	ceph production	glass production	OXISEPT	penem production	plastic production
2017	3.711.621	32.785.151	241.629	5.626.140	242.141.716
2018	6.093.156	31.255.146	186.331	5.689.759	253.611.098



# Leading Greek Hospital Market





# Product Portfolio

DEMO S.A. leveraging its clinical experience of more than 50 years, manufactures and trades high quality products establishing the company to the leading position in the Greek hospital market. The company provides a complete portfolio of pharmaceutical products covering the entire needs of any major hospital.

**01**

## Hospital Market

### Anti-infectives

- Non-beta lactams
- Cephalosporins
- Carbapenems
- Penicillins

### Standard solutions

### Anesthesia/analgesia

### Oncology

### Critical care

### Parenteral nutrition

### Gastric ulcers & gord

### Hematology

### Respiratory

### Central nervous system (cns)

### Medical Devices/ Infusion Pumps





## 02

**Private Market****RX Products**

- GPs
- Cardiology
- Oncology
- Respiratory
- Gastroenterology
- Urology

**Medical Devices**

- Solutions for contact lenses
- Solutions for Eye care
- Cleaning nozzles for nose and ears

**Food Supplements**

- For the Urinary System
- Liver Health

## 03

**Renal Care**

DEMO S.A. started producing its first dialysis products in 1996 via a complete range of haemodialysis solutions. In 1997 our company started distributing the products of a major manufacturer of medical devices for haemodialysis. We concluded an agreement to exclusively distribute their products in Greece, including, but not limited to, haemodialysis machines, haemodialysis filters, fistula needles, catheters, haemostatic pressure bandages & blood lines.

During 2005, our company completed the registration and started manufacturing three haemodiafiltration solutions.

The above activities have placed DEMO S.A. as one of the biggest players in the area of renal services in Greece.

# Production Capabilities

Sterile solutions in plastic (PE or PP) blow-fill-seal (BFS) ampoules (0.5ml to 20ml)

Sterile solutions in plastic bags (50ml to 5.000ml, flexible or semi-rigid bags)

Sterile solutions in plastic (PE or PP) blow – fill-seal bottles (50ml to 1.000ml)

Sterile solutions in glass ampoules (1ml to 20ml)

Sterile solutions in glass vials (5ml to 50ml)

Sterile solutions in glass bottles (50ml to 250ml)

Cephalosporin sterile powder filling in glass vials (10ml/20ml/30ml/50ml vials)

Carbapenem sterile powder filling in glass vials (20ml/30ml vials)

Freeze-dried lyophilized formulations (2R to 50R)  
Ophthalmics (in multi-dose or mono-dose containers)

External Solutions

Medical devices



**Plastic bottles for infusion (Eurocap)**

- Filling volume: 100mL, 200mL, 250mL, 300mL, 500mL, 1000mL  
Material: PP
- Filling volume: 100mL, 250mL, 500mL, 1000mL  
Material: PE-LD



**Plastic ampoules for infusion**  
Dilution for luer-lock and luer-slip syringes

- Filling volume: 3mL, 5mL, 10mL, 20mL / 1mL, 2mL, 3mL, 5mL, 15mL  
Material: PP / PE-LD



**Plastic vials (Eye drops)**

- Filling volume: 5mL, 10mL, 15mL  
Material: PE-LD
- Filling volume: 8mL, 10mL, filled in 10mL  
Material: PP



**Glass ampoules**  
Open and closed type

- Filling volume: 1mL, 2mL, 3mL, 5mL, 10mL



**Plastic bottles for infusion  
(Twin port)**

- Filling volume: 100mL, 250mL, 500mL, 1000mL  
Material: PP, PE-LD



**Plastic bottles for irrigation  
(Screw Head)**

- Filling volume: 100mL, 250mL, 500mL, 1000mL  
Material: PE-LD



**Plastic bottles for irrigation  
(Twist-off)**

- Filling volume: 1000mL  
Material: PE-LD



**Plastic flask**

- Filling volume: 100mL, 240mL, 1000mL  
Material: PE-LD



**Plastic ampoules for Medical  
Devices**

- Filling volume: 5mL, 10mL  
Material: PE-LD, PP



**Plastic ampoules monodose**

- Filling volume: 0.5mL Material: PE-LD



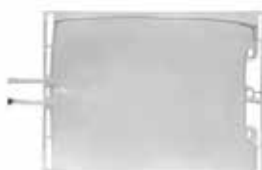
**Nebules for inhalation**

- Filling volume: 2.0mL, 2.5mL  
Material: PE-LD



**Plastic bag - Rigid bag**

- Filling volume: 50mL, 100mL, 200mL, 250mL  
Material: PP



**Plastic bag - Soft bag**

- Filling volume: 300mL, 4000mL  
Material: PP / PVC



**Plastic bag  
Three-compartment soft bag**

- Filling volume: 1000mL, 1500mL, 2000mL, 2500mL  
Material: PP



**Pecanister**

- Filling volume: 1000mL, 5000mL, 6000mL  
Material: PE-LD



**Glass vials - products lyophilized**

- Filling volume: 1mL, 2mL, 3mL, 4mL, 5mL, 10mL, 12mL, 12,5mL



**Glass vials - Dry injectable**

- Cephalosporins  
Filling volume: 250mg, 750mg, 1g, 1.5g, 2g filled in 15mL, 20mL, 30mL, 50mL
- Penem  
Filling volume: 0.5mL, 1g, filled in 20mL, 30mL



**Glass bottles**

- Filling volume: 50mL, 100mL, 200mL filled in 250mL

# Research & Development

## Investing in innovation

Over 50 years of operation, our product portfolio has grown significantly providing the basis for the company's success. To sustain this in the future, the Board of Directors has committed to develop 8 to 10 new products per year and launch them in the global market as soon as they go off-patent. Furthermore, a number of new research projects are under progress that will allow DEMO to experience a dynamic growth in the future.

For this reason, we have invested in the establishment of our modern and high tech Research & Development laboratory. DEMO's R&D lab spans more than 1,600 m<sup>2</sup>, is equipped with the latest instruments and is staffed with top scientists. Under the supervision of highly qualified researchers – most of whom hold PhD degrees from the most acclaimed universities in Europe – our R&D lab represents the company's launching pad for the following decades.

## Dedicated Department of Regulatory Affairs

Hence, in 2005 we reorganised our Regulatory Affairs Department staffed with 21 full time regulatory officers responsible for the preparation of files for submission and approval to the appropriate regulatory authorities worldwide.

Our products' registration files are all in CTD (Common Technical Document) format, which allows us to quickly and efficiently proceed with submissions in EU and non EU countries.

Our participation in national, mutual (MRP) and decentralized (DCP) registration processes have deemed our regulatory affairs department as one of the most competent. Lastly, we have dedicated regulatory officers that constantly monitor local & regional regulatory conditions, providing immediate response in case there are any changes in local requirements.



## Committed to Quality

Since the company's establishment, the quality of our products has consistently been our top concern. For this reason, throughout the company's history, we have heavily invested in the modernization and improvement of our production premises as well as our Quality Control Department.

This resulted in the use of production processes with a high degree of automation, while the technological certifications of our production units are also the top:

- cGMP certification (current Good Manufacturing Practices, current good manufacturing practices)
- ISO 9001

Additionally, our new Quality Control Laboratory has an area of more than 1,600 m<sup>2</sup>, it has been distinguished as one of the best in Europe and is fully equipped with state-of-the-art technology. Moreover, our long - standing cooperation with the Chemistry and Chemical Divisions of Athens University offers us an unlimited source of talented people for staffing our laboratories with leading scientists.

# Quality Assurance







**Our operation  
is based on  
three principles:  
prediction,  
proper planning  
and continuous  
monitoring**

## Quality comes first

The core objective of the Quality Assurance Department is to create production processes that ensure the accuracy and repeatability of the result at every production stage within the framework of the legislation and in compliance with the applicable standards (GMPs, GDPs, ISO 9001:2008, ISO 13485:2003, DY8/1348/04).

The activities of the department include the detailed design of new production areas and the inspection of critical partners and suppliers of the company, in order to ensure constantly high quality products.

The Department is staffed with experienced scientists of various specialties and 4 independent groups, one for each wing of our production.

The Quality Assurance Department has managed to combine the requirements of different pharmaceutical regulations which are different in each country of the planet and integrate them smoothly into its quality system. This has led to the successful audit of our company by strict Legislative Authorities from around the world and has established the high quality of our products.

Our qualification & calibration team maintains a list of all critical instrumentation and ensures correct calibration (both initial and periodic, based on a schedule dependent on Instrument criticality), ensuring the accuracy of all measurement and process data.

The international recognition of these efforts led DEMO S.A. to provide consulting services to other companies worldwide as for them to design and upgrade their productive and quality operations.

### Inspections received by the company between 2016 - 2018 Success Rate: 100%

Year	Customers	Authorities
2016	7	6
2017	8	8
2018	9	6

# The Human Capital



Our leading position in the market is due to our ability to attract and retain the most competent employees according to our principles and values. We strive to provide a working environment that is both safe and motivates the workers and also the people are treated with respect and given equal opportunities for the development of their skills and evolution.

We base the relations with our workers in the principle of equal treatment. Both the integration and the progress of each employee within the Group are judged on the basis of his qualifications, performance and ambitions, without any discrimination.

## Human Rights Equal Chances Policy

The Group monitors the relevant labor law (national & European), including reports on child labor, respect for human rights and working conditions and is in full compliance with collective and relevant international conventions.

# Taking care of our People

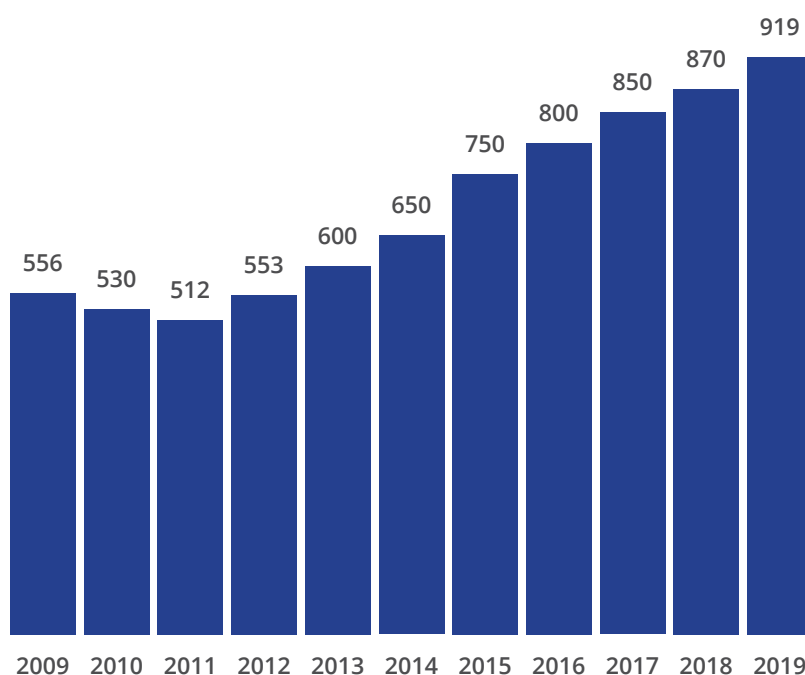
Employees are the most important factor to our development and success. In DEMO, we steadily invest in our people and also in the new scientists of our country. The direct contribution of our people alongside with their efforts had made DEMO one of the leading pharmaceutical companies of South-eastern Europe.

## Increase in Employment Posts

Each year, DEMO is steady developing, increasing at the same time also its employment posts. Since 2015, the company created 167 new employment posts raising its staff from 752 to 919 employees. Out of these posts, 66 were created from early 2018 and this number

is expected to be further increased. The company's developing course contributes to the decrease of unemployment, the boosting of the economy and the local community and the brain-drain limitation.

## The employees



## Employment Details

The mean age of employees is 38 years, 59% under 40 years old and their mean time of employment is 6.3 years. 55% are male and 45% are female. 100% of our staff is employed by virtue of full-time contracts.

The company monitors the working times of all employees, maintains the time limits of employment, defines the times for breaks and rest and it grants all the provided leaves.

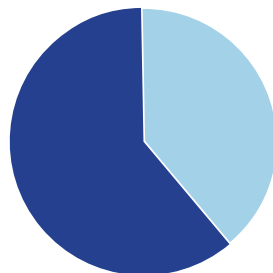
### 38 years

It is the average age of employees

The minimum wage for employees is greater by 46% that the respective legal minimum wage

**59%**

of the Workers are below the Age of 40

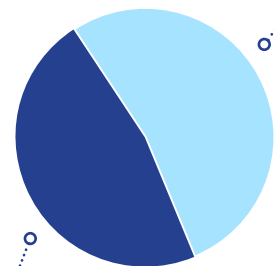


**55%**

Men Workers

**45%**

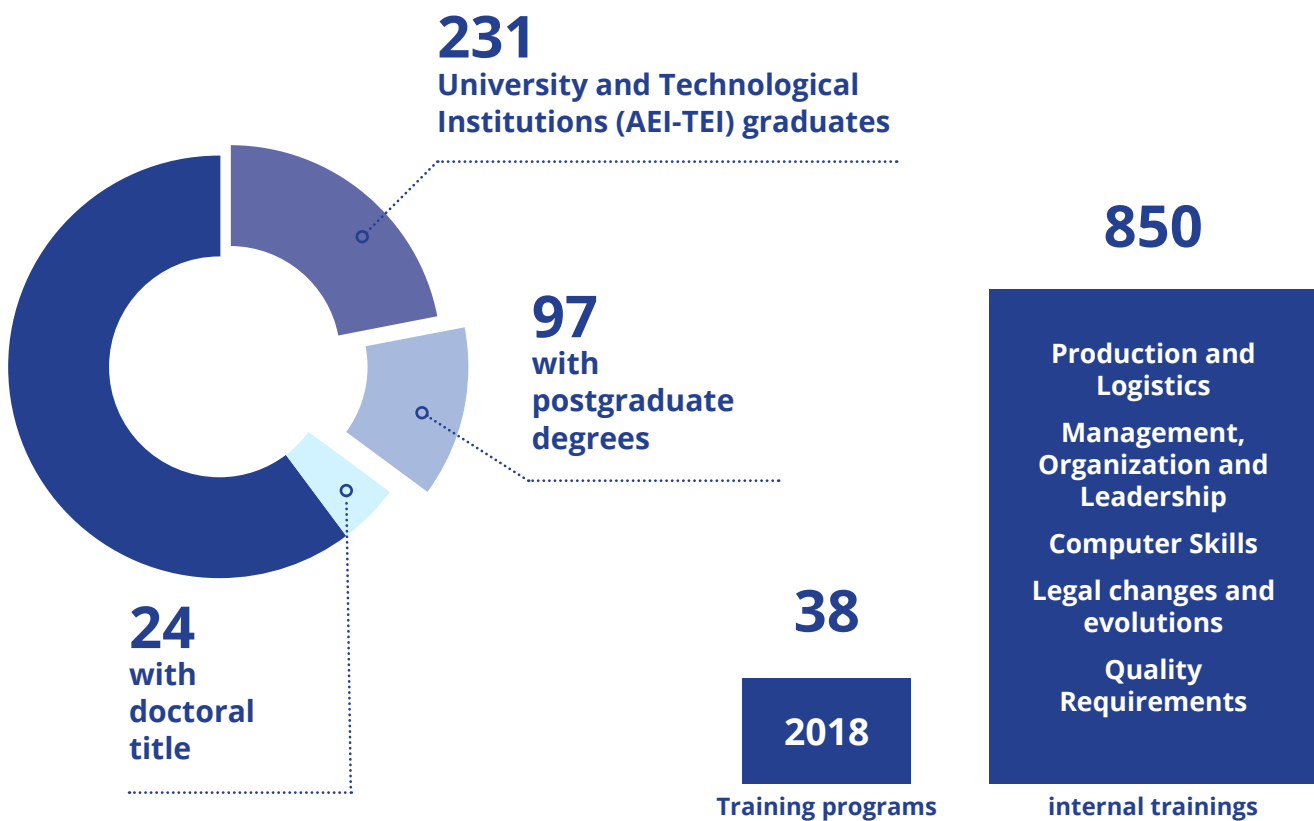
Women Workers



## Education & Training

DEMO has available highly trained human resources and focuses particularly to the education, training and development of its employees. 24 employees with Doctorate title, 97 Post-graduate degree holders and 231 graduates of University and Technical Schools are working with DEMO. Every year, the company finances Post-graduate programs for its employees investing in their progress in the future. During 2018, DEMO employees participated in total in 38 training programs organized by specialized bodies in Greece and abroad in a wide range of subjects such as Drug Production,

Storing and Distribution Techniques, Management, Organization and Leadership, IT Skills, Legal amendments and developments, Quality Requirements etc. At the same time, it maintains a strong internal education program in operation and production procedures within the framework of its more than 850 internal trainings took place in 2018 where almost all employees took part. The company kept investing in the team of internal trainers, promoting and upgrading the employees in the Production department.



## Introduction of New Employees

The company implements a fully structured system of introduction and training new employees in which:

- 1** Employees are fully informed about the company, the structure and the products
- 2** They are trained in matters of Hygiene and Safety
- 3** They are trained on Good Manufacture Practice Rules
- 4** They are informed on the procedures and the rules of organization and operation
- 5** They take their Job Description and a training plan on the procedures that are linked to their job
- 6** They are informed on benefits for the personnel, company actions towards the personnel and matters of company responsibility
- 7** They take their contracts and all legal documents immediately before they start working
- 8** They take immediately the Means of Personal Protection and the special clothin they need
- 9** They are guided in the premises of the company

## Efficiency and Talent Management

The recruitment of talents, the maintenance, development and professional progress of our people is an important priority. We work closely with the Academic community and Secondary education institutions giving to talented students the opportunity of internship through their faculties and their future employment. Many employees started their career as interns and they moved on and became high-ranking officers of our company. At the level of talent recruitment, we took part in career days and we organized visits of new students and graduates in our company.

In 2018, DEMO invested in the development of a new "Start Your Journey" program of scholarships and internship. The program focuses on students with honors under 29, Chemists, Chemical Engineers, Pharmacists, Biologists, Mechanical Engineers and Electric Engineers and Automation Engineers in order to support them in the beginning of their career.

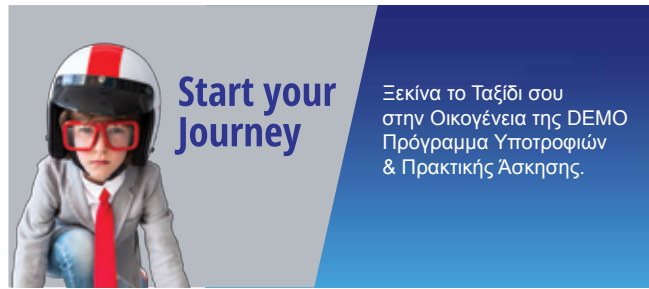
In 2018, 11 Scholarships and 11 Internships were granted and the program still goes on in 2019. This way, DEMO is standing by the new Scientists of our country in an active way. At the same time, in 2018 we started the implementation of a new management system with regards to the employees efficiency of the company and we are investing in the development of an enhanced assessment and rewarding system for the human resources. Our goal is to help employees progressing, developing new skills and to keep their career in DEMO. Together we have developed a strong link: the DEMO "Family"!

## Health & Safety

DEMO makes important investments in the Health and Safety Field of its Employees. It controls in detail and systematically enhance the safety in the counters and the working conditions.

It offers to its staff a fully equipped general infirmary and nurse, and furthermore in its effort to support female employees and the wives of its employees, has established a collaboration with a gynecologist and offers OB practice services. The company offers insurance coverage for life, accidents and health to the employees and an advantageous insurance plans for their families.

The company conducts annually medical exams to its personnel and also specialized tests, such as an audiogram or spirometry, as required. The air quality and sound levels in the facilities are measured. It has established partnership with freelance specialists in matters of security and it conducts inspections and checks. It strictly controls access to its premises.



**Start your  
Journey**

Ξεκίνα το Ταξίδι σου  
στην Οικογένεια της DEMO  
Πρόγραμμα Υποτροφιών  
& Πρακτικής Άσκησης.

## Additional Benefits

In recognition of the role of its employees, DEMO offers a series of additional benefits, apart from its legal obligations for their support.

In particular:

- We are offering to our employees minimum wages greater by 46% than the respective legal minimum wage
- To all employees, along with the open-ended employment program, we offer a health insurance plan
- To all employees, along with the open-ended employment program, we offer a life and accident insurance plan
- We are granting training programs and Post-graduate degrees
- We offer special prices to affiliates, such as gymnasiums, mobile telecommunications, high-tech stores, private insurance plans etc.
- We have a fully equipped infirmary and we are offering gynecological examinations to employees and their wives
- We are organizing fiestas for employees and their children
- We maintain Blood Bank
- We are supporting volunteering actions and teams, such a football team, participation in Marathon race, theatrical team etc.
- We have a bus for transport to and from the company.

# **DEMO S.A.**

## **The best employer brand in Greece, in «pharma» sector**

research «Randstad Employer Brand (REBR) 2019»,  
Randstad

### **150 largest companies in a number of staff**

The interviews involved 4,329 people, including Greek students, workers and unemployed aged 18 to 65. The interviews took place online between 6 December 2018 and 21 January 2019.







Growth Awards  
ΑΝΑΠΤΥΞΗ • ΑΝΤΑΓΩΝΙΣΤΙΚΟΤΗΤΑ

Υπάρχει ένα ελληνικό  
σκεύασμα που θεραπεύει  
ανθρώπους σε 85 χώρες

DEMO S.A.  
Growth Awards 2018



# Awards

The successful performance of the Greek pharmaceutical company **DEMO S.A.** in the business arena set it apart from the rest of the field, having won 18 major business enterprise, gold awards and praises for its entrepreneurial path and prospect in 2015 - 2019.



## ► Healthcare Business Awards 2018

Gold Award, "Investments"

Gold Award, "Employment"

## ► Diamonds of the Greek Economy, 2016, 2017, 2018, 2019

## ► Salus Index, 2015, 2016, 2017, 2018

## ► Made in Greece 2017

Praise for exports excellence

Praise for industrial excellence

## ► Healthcare Business Awards 2017

Gold Award, "Exports"

Gold Award, "Social Responsibility"

## ► Entrepreneurship Club Kouros 2015

Dimitris Demos, International Performance in Business Sector

## ► Made in Greece 2015

Praise for exports excellence

## ► Greek Exports Awards 2015 Top Industrial Company

Gold

# 02

## CORPORATE GOVERNANCE

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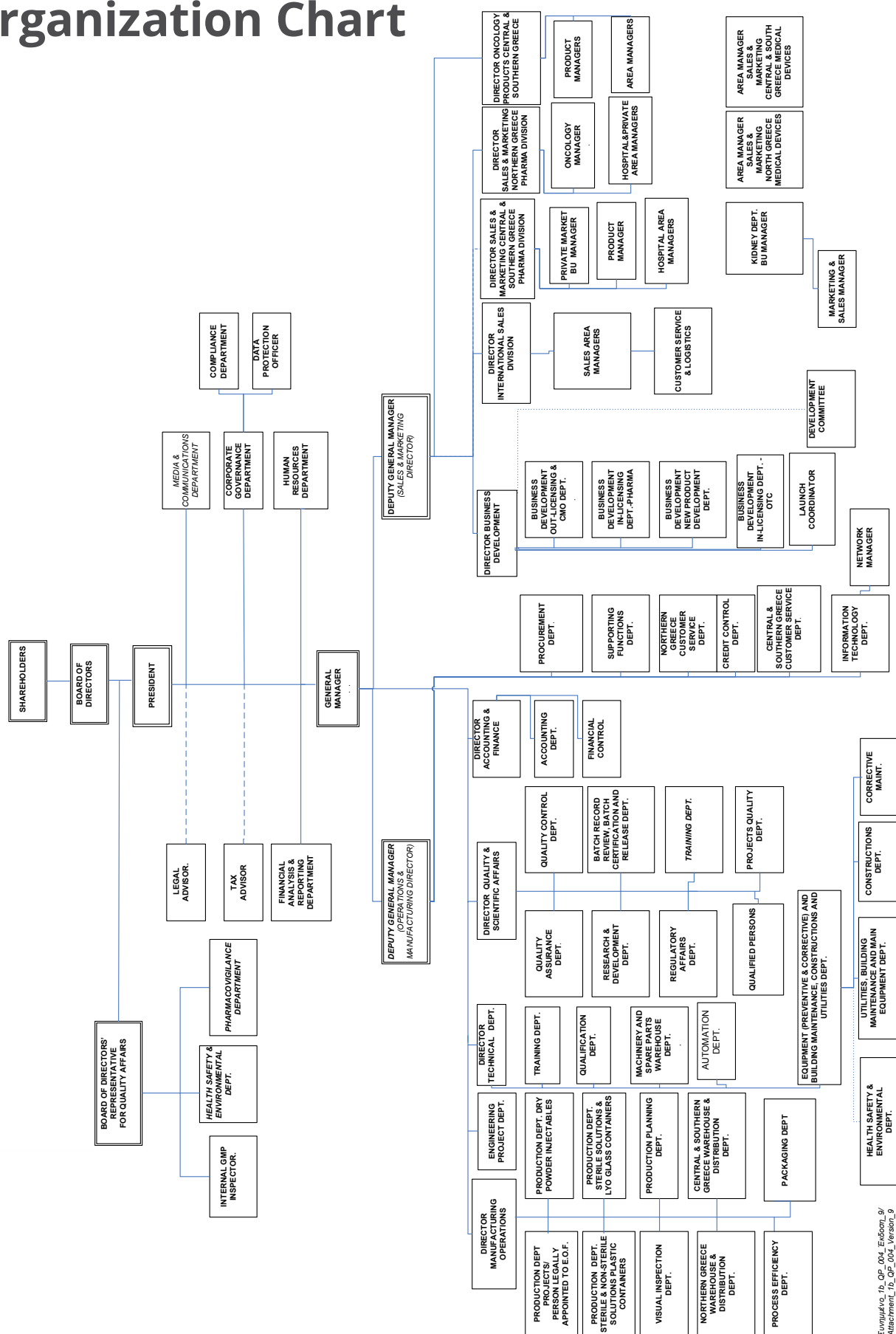
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## Corporate Governance Social Responsibility

At DEMO S.A., based on the principles, values, strategy, activities, market, and community, every year we determine who are the stakeholders that are affecting or affected significantly by our business activities.

This way we aim to establish relationships with these interested parties, so that the industry can react to their needs, minimize the risks for its reputation and operation and take advantage of the competitive advantages created by these synergies.

## Organization Chart



Ευνημμένο\_1b\_QP\_004\_Εκδοση\_9/  
Attachment\_1b\_QP\_004\_Version\_9

# Social Partners

Our commitment to take into account the expectations and the needs of the Social Partners- which interact with our activities within and outside the boundaries of our facilities- is illustrated in the following diagram.



# Business Associates

## Market

### We are promoting and protecting the Principles set out by the Universal Declaration

The UNO Universal Agreement is a politics platform and also a practical framework for the companies that have engaged to sustainability and responsible corporate practices. The initiative of the leaders with participation of many members is to align corporate activities and

strategies with 10 worldwide accepted principles in the fields of human rights, employment, environment and anti-corruption and to promote actions supporting the wider objectives of the United Nations Organization.

### 10 Principles of Worldwide Agreement with UNO are developed and provide for these fields

- Human Rights
- Working Conditions
- Environment
- Fighting Corruption



## Risk Management in DEMO

Risk management is a core element of strategy management of every company, and so it DEMO's. We aim at adding the greatest sustainable value to all company activities. We put in order the comprehension of possible benefits (upside) and threats (downside) of all the parameters that could affect us. We increase the chances of success and we reduce both the chance of failure and the uncertainty about achieving all the goals of the company. DEMO's risk management is a constant and developing process, which runs through the strategy of our company and the implementation of this strategy.

There is a methodic approach to all risks surrounding past, current and particularly future company activities. It is integrated in the company's mentality with an effective policy and a plan with the top administration leading, while translating strategy to tactical and operational objectives, by setting responsibilities at every level of the organization with every administration official and employee being responsible for risk management as part of his job description. It supports responsibility, effectiveness measurement and rewards, in order to promote operational effectiveness at all levels.

## Member of Associations and Bodies

DEMO S.A. is a member of the Hellenic Association of Pharmaceutical Industry (PEF) and also a member of the Hellenic Association of Pharmaceutical Companies (SFEE). The Vice-President of DEMO S.A., Mr Dimitris Demos was re-elected in 2018 as Vice-President of PEF. This Industry is also a member of the Athens Chamber of Commerce & Industry (ACCI) and the initiative "Hellenic Production" (Industrial Roundtable for Growth).

# Business Associates

## Greece Department of Public Tenders & Bids

The Tendering Department has the primary responsibility for the day-to-day monitoring of calls for tender, the collection of documents necessary for the preparation of the dossier, as well as the monitoring of the progress of each tender up to the contract. Prerequisite for the above is an ongoing legal and procedural training in

public procurement, as well as a very good knowledge of online tendering / bidding platforms (ESSEDIS, iSupplies, CosmoOne, etc.).

Our company participates successfully in tenders for the supply of medical devices, services and pharmaceutical products.

## International Tenders 2018

Since the establishment of the International Sales Division of the company, DEMO S.A. has a long and extensive experience and expertise in International Tenders for the supply of Medicines. The majority of our products are procured through the International Tenders, which are announced and managed either by the National Health Authorities of the countries in which we have active product registrations, or by the UN Organizations such as WHO, UNICEF and MSF. Based on strict international standards, these International Tenders are well known in the global pharma market for the demanding specifications and requirements. A successful participation requires completeness in the participation dossier, which means sufficient certification and proof of high product quality. During year 2018, DEMO S.A. participated to approximately 250 International Tenders, with a success rate above 50%. The success is concerning the largest and most important tenders, held for an extensive range of products.

**More specifically, the number of International Tenders we participated to last year is as follows:**

Europe	40
Middle East	42
Asia and Oceania	60
Africa	38
UN Organizations	70



# Business Associates

## Suppliers

DEMO S.A. has a large and complex list of suppliers with more than 839 active suppliers, mainly Greek companies, for the purchase of materials and equipment or the rental of services, which is renewed in the context of the development of a sustainable supply chain.

Our suppliers and associates are selected and evaluated to improve our overall performance in terms of quality, cost and sustainable development.

## For a Sustainable Growth Supply Chain

96

DIFFERENT DEPARTMENTS

839

TOTAL NUMBER OF SUPPLIERS

40

DIFFERENT ORIGIN COUNTRIES  
FROM ALL CONTINENTS

546

GREEK SUPPLIERS

7.789

TOTAL NUMBER OF ORDERS  
WITH AVERAGE 633/MONTH

293

OUTSIDE BORDERS SUPPLIERS

BOXES					
CODE NUMBERS	NUMBER OF RECYCLED CODES	PERCENTAGE OF RECYCLED	QUANTITY OF RECEIVED ITEMS 2018 (TOTAL)	QUANTITY OF RECEIVED ITEMS 2018 (RECYCLED)	PERCENTAGE OF RECEIVED RECYCLED
533	171	32,08%	16.366.605	5.293.685	32,3%

CARTON BOXES SEMI					
CODE NUMBERS	NUMBER OF RECYCLED CODES	PERCENTAGE OF RECYCLED	QUANTITY OF RECEIVED ITEMS 2018 (TOTAL)	QUANTITY OF RECEIVED ITEMS 2018 (RECYCLED)	PERCENTAGE OF RECEIVED RECYCLED
7	7	100%	343.295	343.295	100%

CARTON BOXES FULL					
CODE NUMBERS	NUMBER OF RECYCLED CODES	PERCENTAGE OF RECYCLED	QUANTITY OF RECEIVED ITEMS 2018 (TOTAL)	QUANTITY OF RECEIVED ITEMS 2018 (RECYCLED)	PERCENTAGE OF RECEIVED RECYCLED
150	150	100%	1.712.902	1.712.902	100%

### TOP 10 COUNTRIES

(number of suppliers)

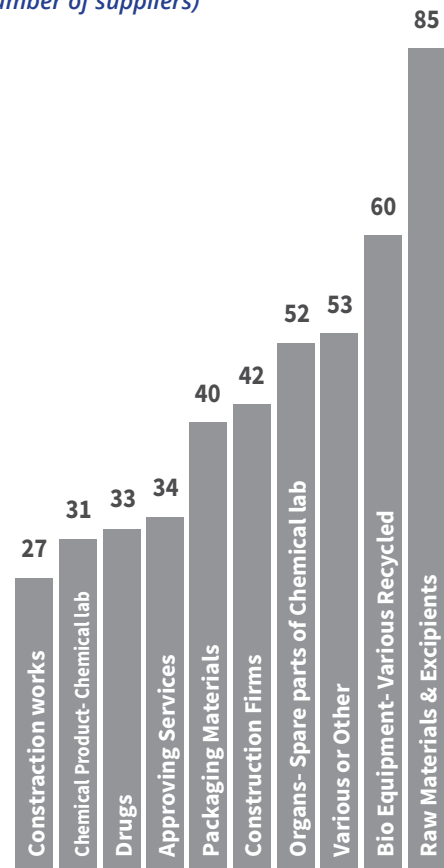


**Greece**  
**546**



### TOP 10 SECTORS

(number of suppliers)



# Compliance Policy

Honesty, Transparency and Human Respect constitute core values of the company throughout its field of activity. At DEMO, we have developed an operating framework which encourages ethical and lawful activity with the principle of integrity as everyone's personal responsibility defining corporate conduct.

The Company has set high priority on issues related to the **compliance policy and the combat against corruption and bribery**. What one calls business integrity expands to all our actions in our circle of activities and also to the framework shaping the work and business relations with both our personnel and our associates. The purpose is to ensure compliance with the applicable Law, regulations and guidelines that govern the pharmaceutical industry. DEMO totally adheres to the whole set of rules and regulations that apply to its industry and constantly develops internal control systems in order to comply with this institutional framework. The complexity of Law, whether coming from the national regulatory framework or from the respective set of international rules, is a common practice in the pharmaceutical industry and therefore, DEMO, within the context of corporate compliance, decodes all applicable rules and regulations and makes them available to all its Personnel. The company's activities are being conducted in full compliance with all national and international laws and regulations that govern this industry, in particular. The compliance procedures we have developed are applicable to all our Personnel and we are seeking that our associates adopt a similar set of procedures, aligned with any applicable Law at the time. We urge our associates to meet the requirements of the Compliance Policy in our business processes as well as in their own business activities.

DEMO has established a program aligned with the regulatory framework that governs its business operations and its field of activity. Our flexibility to

changes/amendments of the regulatory framework allows us to adapt and respond accordingly to evolving compliance needs. This framework of processes allows for the maintaining of a transparent, distinct and clearly understandable "compliance culture".

The Compliance and Corporate Ethics program requires that all Personnel and associates operate in accordance with all applicable Laws and regulations that set high standards of ethical conduct.

The Company pays particular attention to identify potential risks on matters related to corruption, planning and applying preventive inspections in order to have a safety net established with procedures that monitor and report the effectiveness of these mechanisms in managing the company's exposure to risks. Within this context, it resolves any issues that arise at the level of the compliance policy.

## PURPOSE

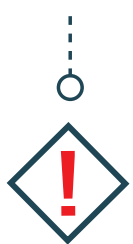
The Development of Internal Procedures and Policies through which corporate integrity is ensured.

## RESPONSIBILITY

Adopting preventive measures for deterring conduct that is inconsistent with the rules of ethics and legal order.

## PRIORITY

The implementation of a culture that ensures the highest possible level of compliance.



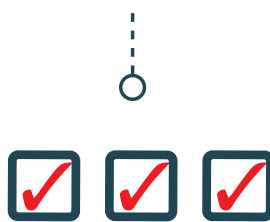
**RULES**



**STANDARDS**



**POLICIES**



**REQUIREMENTS**



**REGULATIONS**

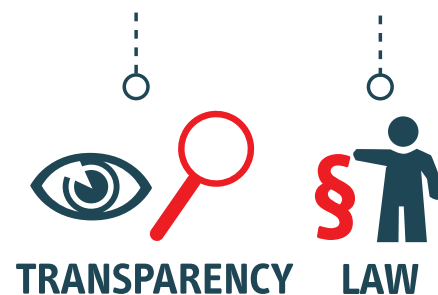
**DEMO, in order to ensure that its compliance practices are understood and adopted by its Personnel, organizes training programs on an annual basis, which every member of the Staff is obliged to attend. The training structure ensures that the employees become fully aware of the compliance procedures, by providing them with all the necessary information, guiding them with regard to their application.** The training takes place annually for all Personnel, and constitutes part of the orientation (introductory) training of each new employee, at the company, regardless of their level of responsibility. The purpose is to ensure that all services are carried out with integrity and professional ethics, ensuring that all Personnel have knowledge and comprehend the applicable institutional framework against bribery and corruption as well as the code of ethics and that they act according to these. This obligation of adhering to compliance procedures also applies to any other third party-associate, acting on behalf of DEMO and is accordingly safeguarded. This way, our company achieves adherence to all the procedures that have been set up for supporting the compliance program while at the same time it preventing/deterring and detecting any failure to conform to the rules and regulations governing the industry of the field of activity of DEMO.

We consider that the implementation of compliance procedures works to the benefit of both, the company itself and its Personnel. This way, we encourage our Personnel, in the event they detect any conducts or practices that oppose to the set framework of compliance procedures, to contact the Compliance Department for the appropriate corrective action. As a company, we remain committed to preserving our positive image and our good corporate reputation, built over the years, and we demonstrate particular sensitivity to any situations that could adversely affect it. The implementation of all compliance procedures by all Personnel provides maximum contribution to that.

The Compliance Chief is responsible for the development, implementation and continuous improvement of the compliance framework of the company according to the regulatory framework. He/She follows the legislation and the applicable Law to be able to update the compliance procedures which might be affected by any other change in the company's business practices. At this point, we consider the Personnel's contribution to be important

for maintaining a reliable and meaningful compound of compliance procedures and business ethics. As part of the global economy, DEMO operates in such a way as to respond to the fundamental principles of the human rights, work and the environment. The goals for Sustainable Development of the United Nations constitute for our company a challenge for the manifestation of responsible corporate activity, by embedding the Ten Internationally Accepted Principles of the United Nations Organization, one of which is the fight against corruption. Our policy for this principle is being materialized by the compliance program, as it has been developed by our company.

To any actions opposed to the good business practice, by creating a substratum of appearance of corruption point, we apply a zero-tolerance policy, reaching thus, the desired deterring result.



**DEMO** believes that a total compliance program creates a proper operation guarantee mechanism, following the institutional framework of rules, thus acquiring significant additional benefits to its corporate activity, in the direction of ensuring transparency in all levels of its operational structure.

## General Data Protection Regulation, GDPR

**DEMO** acknowledges the importance of protecting the processing of all involved into the operation of the company, data, and within this context, it has adopted the General Data Protection Regulation (GDPR) to its whole. According to the Regulation, the data are subjected to higher standards of protection, in particular the category being treated as “sensitive personal data”. Before the date of entry into force of the Regulation, the 25 May 2018, the Company had developed specific actions which contributed to its unobstructed compliance with the new Regulatory Framework for the protection of all the data categories that it regulates, regardless of the subject, which can be the employees, the associates or/and any other third party involved in the company's activities. DEMO recognizes the essential importance of its employees' and associates' protection of privacy, security and data protection. Applying the GDPR, we are responsibly and legally applying a series of measures for ensuring data protection. Appropriate organizational and technical means, such as, for example, mapping personal data, reducing data volume and their kind, reinforcing cyber security, contribute to the reduction of their use

and their storage as well as to the reduction of their exposure to a data leakage risk. Within this context, the Data Protection Officer (DPO) ensures our obligation and commitment that the organization of the personal data processing is being carried out according to the rules into force.

Following written consent by the concerned subjects, the company processes their personal data with the aim of improving our company activity, to defend our company's interests, the best communication with them, giving all subjects the possibility of direct update and access to these, whenever they desire.

The high responsibility level when it comes to the method of collecting and processing data in the context of a full application of the GDPR, has been certified by a relevant audit performed by a Consulting Company. The transparency that characterizes the company's operation, allows its easier and more efficient compliance to the GDPR. The integrity and the confidentiality, define the responsible and lawful manner by which DEMO manages compliance to the Regulation.

**At DEMO the personal data protection is being carried out in a lawful and responsible manner.**



# Sponsorships & Donations

Within the context of Scientific update and the Healthcare Professionals' training, DEMO sponsors, each year, Conferences of Scientific purpose. Goal of these sponsorships is to enrich knowledge and reinforce scientific information. The Scientific Events, to which the Company participates, comply to the Regulatory Provisions of the NOFM (National Organization For Medicines) and the Code of Conduct of the Hellenic Association of Pharmaceutical Companies (HAPC).

DEMO participates in Research and Training Sponsorships of Scientific Companies, thus reinforcing the execution of innovative research programs in the health sector, aiming to the advancement of Medical Research.

It donates technological equipment to the benefit of Health Institutions, contributing to the improvement of their infrastructure and to the upgrading of their provided services. It donates to Patients' Associations, which target the improvement of the prevention, diagnosis and treatment conditions of particular diseases as well as the supply of information and to raise the general public's awareness.



- DEMO Participations in Conferences
- Sponsorships to Local Conferences
- Sponsorships to International Conferences
- Donations to Healthcare Institutions, Patients' Associations & Contributions to Research Centers

# Systems & Improvements

## Serialization Project

Since May 2018, the IT department has been responsible for the Project Management of the Serialization project. This is a high-criticality project, given the relevant regulatory requirement (**Directive 2011/62/EU**), since non-compliance leads to the inability to conduct sales.

Moreover, the project was characterized by increased complexity: it involved all of the plant's packaging lines and covered the creation and assignment of serial numbers to each unit selling items in the 32 signatory countries, up to the communication of serialized data to a Central EU Managing Body and to the customers.

The project was implemented using Systec Uniseries & UniTrace systems (L1-L5), from the packaging line up to Level 5, in 4 phases spanning a 9-month period. It was put into productive operation on 09/02/2019.

The following factors significantly contributed to the rapid and successful implementation of this particularly extensive project: the proper prioritization of lines and items, the correct and functional structuring of work teams, the drafting and adherence to a correct internal time schedule, as well as the full support of Project Management by the Technical Division and the specialized Serialization Team, through a devoted, uninterrupted hands-on involvement and engagement

## Electronic Invoicing and EDI Interconnection with customers

The last 6 months of 2018 saw the start of the electronic transmission of value-related documents (e-invoicing) to those of our customers who had agreed to the relevant change. The specific project continues the previously implemented **"Archiving & e-invoicing Project"** and finally eliminates the need to print value-related documents, which are now transmitted to our customers only in electronic form.

Also, in early 2019 we started to interconnect with our customers through EDI for the purpose of transmitting documents, so that, in addition to the electronic document, the associated entries could be directly entered into their IT systems, requiring no human intervention but only the exchange of EDI messages.

Both projects were implemented using the Paperless Connect service provided by the company IMPACT and the PDF2EDI solution.

These two projects have helped save 1 more tree annually (approximately 8000 A4 pages), with the related savings of consumables and postal expenses. Moreover, this leads to savings of approximately 66 man-hours annually that would be required for the handling of printouts.

## Business continuity and cyber-security ensuring

To ensure uninterrupted operation of the company's computer systems and applications:

1. The company has a Disaster Recovery Site in case a negative event (technical failure, destruction, etc.) damages the central computer infrastructure and systems.
2. Policy for both On Site and Off Site backup

Additionally, to establish a secure electronic environment, the company's network and IT systems have been tested under GAMP5 to ensure the confidentiality and integrity of company systems and records from risks such as:

1. Computer and program viruses (virus, worms, Trojan, ransomware).
2. Internal threats and unauthorized access.
3. Important data damage due to employee negligence / wrong use
4. External attacks (hacking, phishing mail, spam, social engineering attacks)
5. Safety gaps in software and systems



# Medical team

The Medical Affairs team of DEMO, consisting of the Scientific and Medical Advisor and Clinical Pharmacists, has as its main objective the scientific support of all the company's departments such as: R&D, Business Development, Sales, Pharmacovigilance, Regulatory etc. The primary responsibility of the team is also the 24-hour support of healthcare professionals and patients who turn to DEMO's special contact line (Medical info line) to receive medical and scientific information about company's products.

The Medical Affairs team presents training courses which are addressed to the Sales Department regarding all the new company drugs.

## Figures 2018



Medical Queries

**341**



Promotional materials

**118**



Medical devices

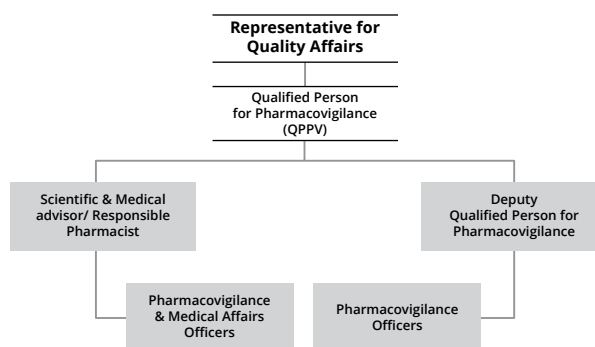
- Clinical evaluation
- Preclinical evaluation
- Risk analysis based in ISO 10993
- Post Market Surveillance Plan report

**9**

# Pharmacovigilance System/ Pharmacovigilance Department

DEMO Pharmacovigilance (PV) department is an independent department whose main role is to continuously monitor and assess the risk-benefit profile of the medicinal products distributed worldwide, as well as to minimize the potential risks ensuring patients' safety.

The highly-experienced PV team of eight (8) people (full time equivalents), with theoretical and practical knowledge of all PV activities required by legislation, is responsible for the establishment and maintenance of a robust and compliant PV system.



The Pharmacovigilance (PV) System of DEMO is maintained by the PV Department of the company, which is headed by the Qualified Person for Pharmacovigilance (QPPV) and supported by the members of PV Department, and it has been planned in such a way so as to perform all the activities according to the EU PV legislation.

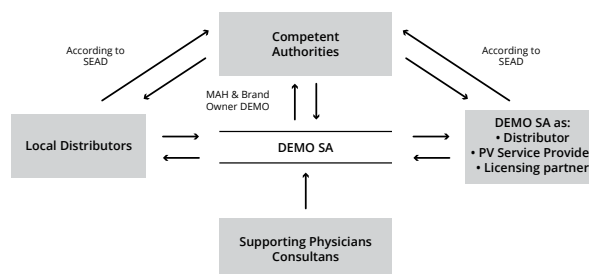
As per the national, European and worldwide legislation for Pharmacovigilance (Regulation No 1235/2010, Directive 2010/84/EU, FEK: 2374/24 August 2012, Good Pharmacovigilance Practices, ICH & national guidelines) the PV system ensures that information about all suspected adverse reactions and other safety data, which are related to products distributed in Greece or abroad, are collected, assessed and recorded in order to be accessible at one point within the community as well as that they are reported to the Competent Authorities (National Organization of Medicines in Greece, European Medicines Agency and other EEA or non-EEA Authorities). All Adverse Events/Adverse Drug Reactions and other safety reports are collected, recorded and assessed by DEMO regardless the source, seriousness, causality or expectedness.

DEMO S.A. acts as the PV service provider for the companies Noridem Enterprises Ltd. and Bradex Commercial and Industrial Pharmaceutical Products S.A. There is a single PV system, which is located in Athens (DEMO facilities) and covers all of its product licences and those of Noridem Enterprises Ltd. and Bradex S.A.

In addition, the PV system covers the national licenses in Cyprus for which DEMO is the manufacturer and the dossier owner, but the company The Star Medicines Importers Co. Ltd is the MAH.

The PV System is described in the Pharmacovigilance System Master File (PSMF) and the PSMF reference number or EV (EudraVigilance) code of DEMO PSMF location is MFL2876.

The interaction between DEMO, other companies and Competent Authorities is presented below:



All PV functions are conducted in-house using a compliant, fully validated safety database [PvEdge, compliant with E2B(R3) format] as well as in accordance with internal Quality System and written procedures.

Registration of DEMO with EudraVigilance (EVWEB) for the electronic reporting of Individual Case Safety Reports (ICSRs) has been successfully completed on November 7th, 2008.

DEMO was added into the XEVPRM (eXtended EudraVigilance Medicinal Product Report Message) community in the Production Environment on June 11th, 2012 (for product electronic reporting purposes). EVDAS users for greater access to EudraVigilance were registered in June 2017.

On 22/11/2017 EMA launched a new EudraVigilance System with enhanced functionalities for reporting and analyzing suspected ADRs. For this reason, on 28/11/2017 the PV database was fully upgraded (and validated all over again) in order to be compliant with E2B(R3) format. In parallel with this update the name of the PV database was changed from PvNET (which was the name of database from 25/02/2014) to PvEdge.

## Metrics during the period from 01/01/2018 - 31/05/2019:

- **235 ICSRs** (Individual Case Safety Reports) were collected, entered and assessed in PV database PvEdge, while a high number of ICSRs was downloaded by EVDAS (EudraVigilance Data Analysis System), assessed and recorded.
- As per EURD list **10 EU-PSURs (Periodic Safety Update Reports)** and **2 responses** related to EU PSUR single assessment procedures were submitted to EMA. In addition, **30 non-EU PSURs** were prepared for registration or renewals purposes of medicinal products in non-EU countries.
- **9 non-EU RMPs (Risk Management Plans)** were prepared for registration or renewals purposes of medicinal products in non-EU countries, while **17 EU-RMPs** (including updates during registration procedures) were prepared for supporting the registration purposes of medicinal products.
- **91,755 literature articles** were screened from the worldwide literature and assessed in PV database for ICSR and signal detection, and assessment of the risk-benefit profile of the medicinal products.
- **11 new SDEAs (Safety Data Exchange Agreements)** were finalized between DEMO and local distributors or other partners, while **26 existing SDEAs** were updated.
- **xEVMPD (Extended EudraVigilance medicinal product dictionary)** was updated with **600 medicinal product** reports, which were submitted to EMA as xEVMPD entries (new inserts or updates).
- In agreement with the European Medicines Agency (EMA) and the Competent Authorities of Member States, **educational materials** and **DHPCs (Direct Healthcare Professional Communications)** were prepared and disseminated to Healthcare Professionals in various EU countries in order to inform them about safety issues related to the administration of **9 medicinal products** of the company and, therefore, to minimize the risks of the products and to ensure patients' safety.
- Continuous monitoring of PRAC (Pharmacovigilance Risk Assessment Committee of EMA) recommendations as well as signal detection and assessment procedure by the PV department concluded to product information (Summary of Product Characteristics and Patient Information Leaflet) update of **29 active substances** with the aim to inform the Healthcare Community and minimize the risks of the products.



## Sustainable Growth Responsible Entrepreneurship

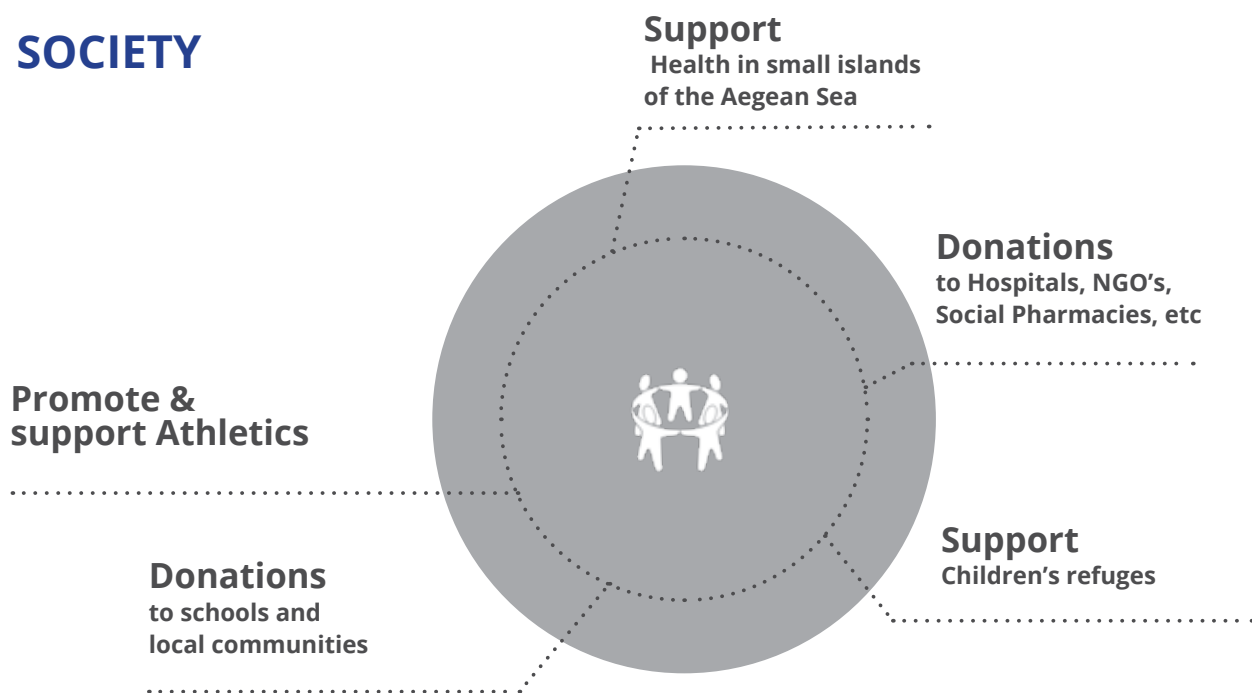


*είναι ευθύνη*  
**μας**

# Social Responsibility in 4 pillars

The Sustainable Growth and Responsible Entrepreneurship  
are a commitment for DEMO

## SOCIETY



## MARKET



## ENVIRONMENT

«Saving»  
**56.976**  
trees/year \*

«Saving»  
**115.134**  
liters of  
water/ year \*

*\*these measurements regard  
the responsible printing for  
the duration of a year.*

Batteries Recycling  
**38 kg**

Oil recycling  
**1.700 kg**

Solid Wastes  
**417,47 tn/έτος**

We support the  
initiative  
"Green Mission"



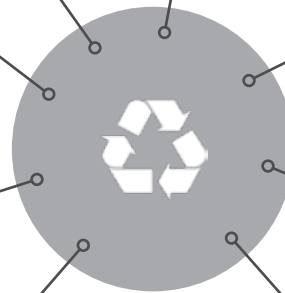
**Total energy saving  
of more than 60%**

(Replacement of conventional fluorescent  
lamps with new LED-type lamps)

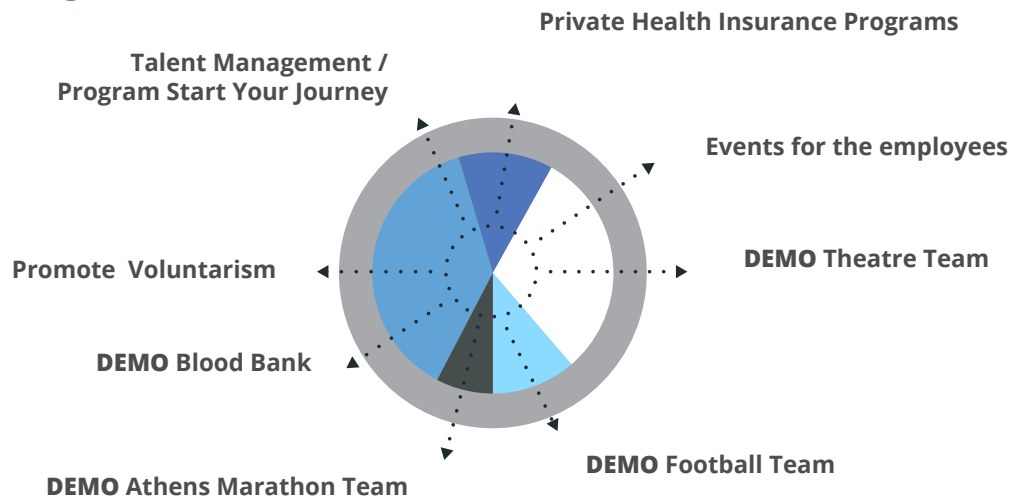
Plastic Recycling  
**1.295,51 tn/year**

Paper Recycling  
**242,29 tn/year**

Recycling of  
electrical equipments  
**717 kg**



## EMPLOYEES





# Health & Safety at Work



## Health & Safety at the working environment (HSE)

### What is Health Safety & Environmental

It is the provision of the necessary means, knowledge and skills to ensure the environmental protection, health and safety of employees during their professional activities.

It is necessary to prevent accidents at work and occupational diseases as well as to protect the environment. For this reason, the work force must be provided with:

- Clear instructions and training
- Means of Individual Protection

### Instruction 92/58/EOK

*Any signage referring to a particular object, activity or condition, provides an indication or instructions on safety or/ and health at work, as appropriate, by means of a sign, color, light or sound signal, verbal announcement or signal by gestures...*

## Continuous improvement

Safe working conditions are not only worthwhile social goals of a modern business but also economic goals, whose achievement contributes effectively to the economic development of a country.

The continuous improvement of working conditions and, more generally, the upgrading of quality in the working environment has been set as a key business priority at both national and European level. At DEMO S.A. we ensure a healthy and safe environment, contributing not only to improving quality of life and working peace, but also to enhancing the competitiveness and productivity of the business.

The capstone of this commitment and our unceasing efforts is DEMO S.A. to granted a certification according to the OHSAS 18001 standard by one of the most accredited bodies all over the world, TUV Nord.

A key parameter for addressing Health and Safety issues is **prevention**, which refers to the appropriate preparation in advance to identify the sources of risk at the premises of the company, to identify in time the risks arising from its operation, assess the corresponding

risk and plan the measures that should be prevented. In addition, similar treatment is required and is done in the possible emergency situations, which must be prepared before they occur.

### In particular

- We have established a Safety Committee, with the participation of all head officers and the representation of all fields of work which examines matters of Health, Hygiene and Safety and communicates the results to the Administration
- We make constant training in matters of Health, Hygiene and Safety, as the treatment and protection from dangerous situations. In 2018, 25 employees were trained in medical care and First aid and 65 employees followed a firefighting seminars.
- We offer the necessary personal protective equipment to all employees and we are monitoring its proper use
- We ensure proper conditions in workplaces (such as temperature, ventilation, illumination, cleaning)
- We record and examine Health and Safety accidents and cases, in order to take over any adequate measures to extinguish risks.

**Apart from the creation of a safe working environment in the areas of production, we also take care to create a safe working environment in offices as well.**

Within this framework:

- We conform to the provisions of L.1568/85 with regards to the Hygiene and the Safety of employees
- We have drafted a comprehensive Safety Measures Plan
- We have created a Department of Hygiene and Safety for the appropriate implementation of safety measures
- We maintain an Events Book and we record there any accidents and incidents at the working areas in order to take over the adequate measures to prevent risks
- We have communicated instructions for the treatment of urgent situations and preventive measures
- For protection, educating at the same time all employees in matters of health and safety (like responding to emergency situations, First Aid and evacuation procedures)
- We have set and communicated an evacuation plan, taking care the safe transfer of employees, visitors and freelancers at prespecified meeting and counting points
- We have appointed a Fire safety Team and an Emergency Care Team, and their members have distinguished roles
- We have established a public address system for announcements of leaving out in cases of evacuation
- We seek to lift any barriers at emergency exits and them to be clearly signed and luminated
- We have anti-slip films at the stairs
- We are forming special working conditions for the safety of office employees that are members of sensitive teams, such as pregnant women and night-shift employees (for which we are taking over additional safety measures)
- We ensure proper conditions in workplaces (such as safety, air conditioning, ventilation, illumination, cleaning)
- We ensure easy access to people with disabilities in the offices (such as parking lots with ramps, wheelchair, toilets with people with disabilities)

It is worth to note that:

- We are among the first pharmaceutical industries in Greece that implemented and got accredited with the International Standard OHSAS 18001
- There are no employees with great chances to present or risk to suffer from work-related diseases, while there was no incident of employment-related disease among our employees
- Just some minor incidents were noted which caused minor injuries in 2017 and 2018, without any of them being related with an office employee.



### Environment

Our main commitment is to have an environmentally-responsible operation and to conduct our activities in a way restricting our environmental impact which is inadvertently caused by our operation. We are among the first pharmaceutical industries in Greece that implemented and got accredited with the International Standard ISO 14001.

Within this framework:

- We are recording our environmental performance. On an annual basis we are evaluating our environmental impact through the Environmental Management System that we are applying
- We are training our employees in matters of environmental protection and we proceed to internal training to all of our employees in matters like waste management and responsible use of water
- We are managing our climate footprint. For the management of our climate footprint and the more efficient energy consumption: We have installed sunscreen films on most parts with windows in our buildings. We have replaced our old water coolers with new ones with higher efficiency degree. We have introduced automatic procedures in the BMS system in our offices and also in the production for more efficient cooling/heating and we have implemented a series of interventions leading to the more efficient energy management, such as the installation of specialized control sensors and heat exchangers, planning and communication of critical notifications, and also scheduling for the reduction of energy cost. We have placed energy saving lamps (LED) in our company's offices and also at the warehouses. We are turning off electric devices when they are not in use. We are buying office equipment (e.g. computers and screens) with 'energy star' specifications.



**For DEMO successful entrepreneurship is not only a synonym to the company's development and the positive financial results but also social responsibility actions and sustainable development**

Within this framework, our company takes over initiatives that support sensitive social groups by providing free medicines, materials and machines to regional medical practices at the islands, Non-Governmental Organizations, social pharmacies and more. Our company recycles astonishing quantities of plastic and paper and it has its own management means for the collection of solid wastes and their transfer for destruction.

DEMO ensures the implementation of sound management procedures with regards to its buildings and facilities and the recording of carbon emissions, saving at the same time energy using modern illumination systems.

Apart from the private insurance and health plans that cover all our employees and apart from the company's infirmary that is equipped with modern devices, our company proceeded to a collaboration with an Obstetrician, Surgeon - Gynecologist who has been offering without any charge his services since 2017 in a special room in our premises to every woman employee who would like to discuss about any gynecological matter.

**To this purpose, we created a gynecology office, where women employees of DEMO are getting TEST PAPs and/or breast examination on time and for free.**

This innovative initiative, is an offer to the women employees who are 450 in number, and it is an innovation for both Greek and European standards in private sector.

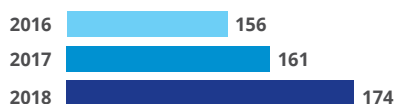
Finally, our company produces specially-composed pharmaceutical products for rare diseases, which are ordered even for one single patient, upon the granting of a special approval by the Authorities.

DEMO's willingness to stop a production line of **15,000 bottles per hour for 8 hours** in order to produce **20 or 30 bottles that will save a man or woman**, is perhaps the most important act of social responsibility.

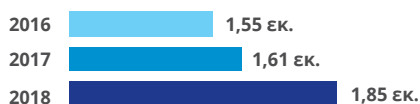
# Social Footprint

## Patients' Support

Number of diseases for which treatment is offered



Number of patients receiving treatment



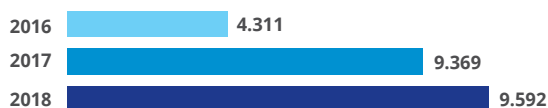
## Research & Development

Number of employees working in Research & Development

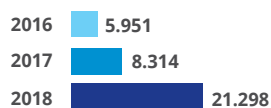


## Care for Society

Quantity of pharmaceutical formulations that has been supplied for free (packaged) in order to cover emergencies in response to natural or humanitarian destructions



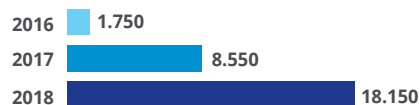
Value of pharmaceutical formulations (€) administered for free



Number of employees-volunteers participating in Social Responsibility actions



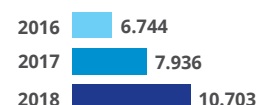
Total number of hours in voluntary work of employees



Number of collaborating bodies/NGOs in the planning/implementation of Good practices



Total number of hours of training as internship



## Social Dialogue

In the period 2016 – 2018 we were subjected to **44 inspections performed by clients and Legislative Authorities** in which we succeeded at a rate of 100%

In period 2016 - May 2019, we welcomed **10 visits of students** from Greek universities, pharmaceutical and technological sectors

Company **website** and company profiles in **social media**.  
FB page: 3350 fr.,  
In page: 5193 fol.



We are sending **monthly info** to our employees which we are posting also in special boards within our premises.

We write and issue a **company newsletter** which is distributed to employees and other partners.

Our company has been **awarded prizes** for its Social Input in various events of the field.

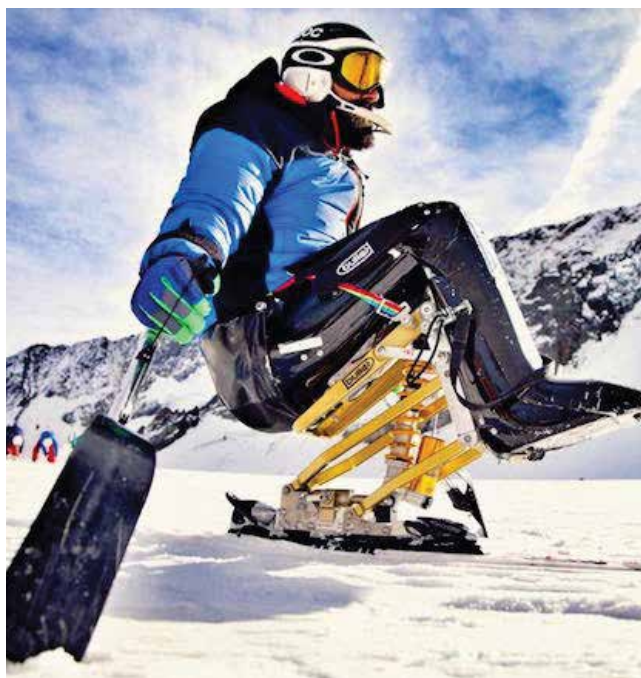
## Stanford University Visit

In March 2018, 15 post-graduate students of the Stanford University visited DEMO's premises within the framework of their annual visit to a European country. Stanford University is one of the leading university all over the world and its alumni have founded some of the most successful companies worldwide, like: Hewlett-Packard, Sun Microsystems, Nvidia, Yahoo!, Cisco Systems, Silicon Graphics and Google. During their visit in Athens, students coming from 7 different countries, including one student from Greece, holding degrees in medicine, biology, technology and political science came to DEMO to discuss the Greek financial situation and matters regarding employment and investments. DEMO welcomed the students with a great pleasure for their choice to include it in their schedule and presented to them in brief its 50-year history in the pharmaceutical field, while it gave a tour to the new scientists in the premises of the Research and Development, Quality Control departments and in the production areas.



## Actions





## Sports and National Representation

DEMO S.A. is the **proud sponsor of Paralympic Alpine ski athlete, Makis Kalaras, for the 5th sequential year** while it keeps supporting for the **4th year the young fencing athlete of Panathinaikos, Savvas Kavvadias**, in his participation in European and World Championships. Finally, since late 2017, DEMO has been **supporting a new and great sailing athlete**, who also currently holds the 9th position in the world ranking of his category, **Panagiotis Matsade**.

Panagiotis is a member of the National Sailing Team U20 in boats category 420 and he has received distinctions in all of his participations both in Greece and Internationally.



## Voluntarism

Employees' volunteer help is also at the core of DEMO's social offer. **In May 2018, a day of volunteer blood donation was organized for the 12th sequential year for the company employees.** Blood units collected every year are placed in DEMO's Blood Bank and they are available to cover any needs that may arise for the families of its personnel. The also gathered voluntarily cloths, shoes and many other items for the refugees hotspots which the handed to **Red Cross**, while the company supports Organization MAKE – A – WISH Hellas by buying wishing stars for Christmas and by participating in Athens Marathon with its team. Finally, apart from the DEMO Football team, that won the 2019 5 X 5 tournament organized by SFEE, there is also a theatrical team for employees aiming to give children performances in NGOs, Children Hospitals etc.



**12 Years of DEMO S.A.  
Blood Bank**

**Gathered 900  
Blood units**





### «panDEMONium», the theatrical team of the company's employees, at the afternoon of Good Monday and Good Tuesday visited Children's Cancer Clinic

**panDEMONium** team worked with the **Creative Learning Action of the "The Smile of child" Organization**, whose everyday task is to visit children's hospital and divert little patients with games and activities.

**DEMO's employees theatrical team "panDEMONium"**, performed acts of the children's theatrical play **"ODYSSEVACH"**, written by **Xenia Kalogeropoulou**, and at the end of three of its performances gave gifts to the children either in the playing room or in their rooms. They gave their performances on Good Monday 22/4 in the Hematology and Oncology Department and on Good Tuesday 23/4 on the 2nd floor, in the floor Special Treatment Center and the Cancer Department of the Aglaia Kyriakou Hospital. panDEMONium team of DEMO S.A. shall continue its performances in the period 2019-2020 in order to offer joy and some relief to young or older people.



In summer 2018 **after the deadly fires in Mati and the destruction of Kinetta**, our company responded immediately to the invitation of the Social Pharmacies of the Municipality of Marathonas and the Municipality of Megara and it sent company serums to cover caring needs for the residents and all pets who have suffered injuries.



**DEMO Pharmaceutical Industries, present in the 36th Classic Athens Marathon, 90 employees took part for a third year running with the "Make A Wish" team.**

90 DEMO employees were there!!! Running at the 5 km and 10 km race and also one runner participated in the classical course of 42 km. Being moved and proud they run as a team for "Make A Wish". Within the framework of the Company Social Responsibility plans, the DEMO administration and its employees have made their priority to support in practice social organizations who help children, and their collaboration with the "MAKE A WISH" Organization dates back to 2015.



**It supported the Organization "Couers Pours Tous"** in the concert they organized this Winter at the Megaron Mousikis (Concert Hall) of Athens with St. Korkolis and Nicola Piovani, and its earnings will be offered to the Institution: In order for children with inherent or acquired heart diseases in developing countries and low-income classes.



**"House of MANA" has a new website sponsored by DEMO SA.**

The company supported the "House of MANA" Organization, **as it undertook the cost for the development of its new website [www.manaorg.com](http://www.manaorg.com) and also the cost for the social media management for it.**

Charitable organization MANA is a new non-profit initiative created based on the personal experience of one of its founding members who suffered breast cancer and its victorious battle against the disease. From the first moment of its establishment, DEMO took under its wings this organization, which is exactly what is denoted by its name (The House of MOTHER): a space with homey warmth that any woman suffering from breast cancer or any type of female cancer can visit. The House of MANA, based in the center of Athens, has been adequately equipped for every woman to feel that she is in a place where she can receive care absolutely adjusted to her special needs and that she can address specialists in order to find support in her health matters.





### At Christmas 2018, the company made donation to Non-Governmental Organizations supporting children

- **Donated money to the Hellenic Union of Parents & Guardians and Friends of Disabled people named "HERMES"**. The amount granted by DEMO was used by "HERMES" for the purchase of necessary items, electric devices and furniture for the restoration of the guesthouse of younger and older children.
- **Donation of money to Make a Wish Hellas Organization** in order to support its work and to make even more wishes come true for children who are in need due to serious or even rare diseases.
- Furthermore **Pharmaceutical Industry, faithful to the relationships it has been developing for years with our Organization "The Smile of the child"**, it bought wishing cards and small gifts – charms from its workstations to support its work
- **Finally, 800 books with Jules Vern novels and 900 books with cd for the teaching of English language** were given to "The Smile of Child" (14 guesthouses all over Greece), "Make a Wish" and DEMO Northern Greece to the orphanages "Melissa" and "Papafeio", "Greek Children's Village" in Fyliro and the SOS Children's Village.



DEMO supported as a **Great Sponsor** the project and the actions of "AGONI GRAMMI GONIMI" (Turning Marginal Routes Fertile) 2019. The project "Agoni Grammi Gonimi" is the greatest educational, cultural & sports project running at the islands of the Aegean Sea and also since winter 2007 up to this date more than 800 visits to 39 islands have taken place. This year this plan lasted from January to June to the following islands: Donousa, Therasia, Apeiranthos of Naxos, Santorini, Kythera, Astypalaia and Karystos.



**Every spring and summer, DEMO shows particular interest for the smaller islands of the Aegean sea** and also the last few years it supports with medicines and sponsorships the organization **"Aegean Team" and the annual crossing of it**, the island Marathi where the company sends annually medicines and medical equipment for the touristic period, and also the **International Music Festival in Molyvos of Lesbos**.

## **DEMO S.A. PHARMACEUTICAL INDUSTRY**

21<sup>st</sup> km Nat. Road Athens-Lamia  
145 68 Krioneri Attica, Greece

**T:** + 30 210 8161802

**F:** + 30 210 8161587

**M:** [info@demo.gr](mailto:info@demo.gr)

**W:** [www.demo.gr](http://www.demo.gr)

