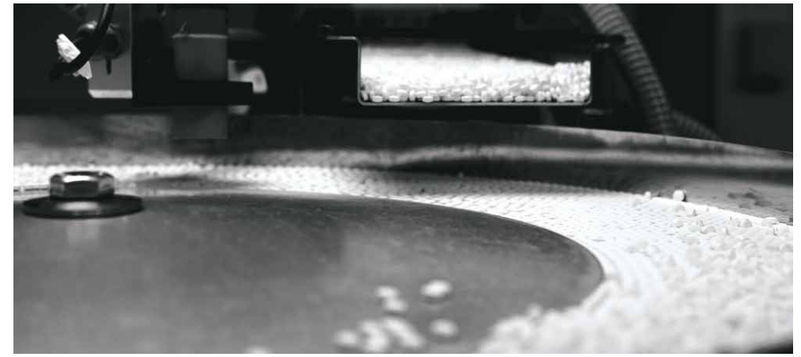
We

Aim

On Innovation



Our Progress

The Company

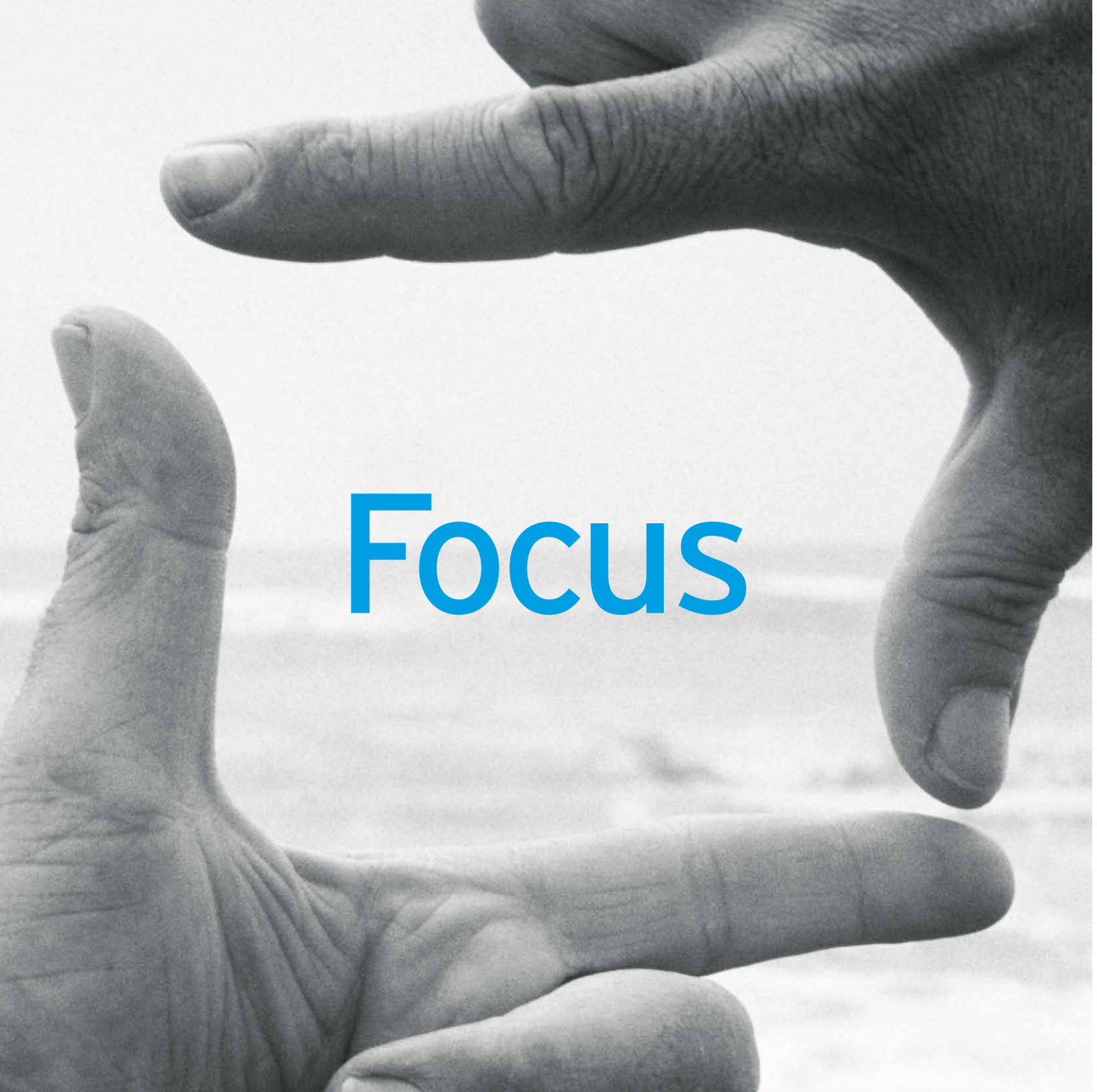
GENEPHARM, a privately held pharmaceutical company, since 1971, has been committed to the development, manufacturing, and distribution of a premium range of generic pharmaceutical products. Genepharm initially focused on the Greek Market, where direct sales were made under its own brand. The company has expanded and now sells its products across Europe, the Middle East, Africa, Asia and the Americas. In 2019 MS Pharma, a fast growing pharmaceutical company based in Jordan acquired Genepharm. In 2021, GENEPHARM was acquired by GMS Holdings.

The Areas

- Greece: manufacturing, sales and marketing of its own branded generic pharmaceutical products
- Europe: product development and out-licensing of its product dossiers, intellectual property and regulatory affairs
- International: out-licensing, technology transfers and distribution of its pharmaceutical products

The Milestones

- 1971: Foundation of Genepharm
- 1974: Inauguration of production units
- 1986: Expansion of activities to international markets
- 2006 - 07: Establishment of sterile liquid and solid oral formulation facilities for oncology
- 2010 - 19: Certifications according to cGMPs compliance standards (GCC, ANVISA, EAEU)
- 2019: Acquisition of GENEPHARM by MS Pharma
- 2021: New Acquisition by GMS Holdings
- 2023: Company operation in the USA
- 2024: Inception of a new R&D Center in Pikermi, Athens



Focus

Our Business

Product Development

- Experienced Scientific Team focus on delivering several new generic products every year
- Targeted Product Development, including “generic plus” products
- Full Patent Search and Assessment, Formulation and Analytical Development. Pilot Scale Production and Stability Trials ensuring industrial application
- Strategic Partnerships and Co-Developments
- Newly completed Laboratory Development expansion to allow the delivery of more generic products every year

Achievements

Having secured agreements for its products with the leading generic companies in Europe and around the world, Genepharm is focused on forging strong and long-lasting relationships with its partners. Genepharm aims to deliver several new generic products per year to its customers. Complex Drug Development will be key to our success in the future and our aim is to be a supplier of choice for quality generic products.

Regulatory Affairs

- Preparing and coordinating documentation
- Ensuring product compliance with the latest regulations
- Vast knowledge and database, collating a wide range of information from around the globe
- Compilation and submission of eCTD dossiers to Regulatory Authorities
- Extensive experience and knowledge base to reply to deficiency letters and efficient support to all regulatory procedures
- Communication with Regulatory Authorities for DCP’s, MRP’s and National Procedures to facilitate Marketing Authorizations
- Maintenance of eCTD dossiers
- Maintenance of the life cycle of the Product

Accreditations

- ANVISA GMP
- EAEU GMP
- EU GMP
- GCC GMP
- Health Canada
- ISO 14001:2015
- ISO 50001:2018
- ISO 9001:2015
- Iraq GMP
- Jordanian GMP
- Korea Ministry of Health
- Kurdistan GMP
- Pakistan GMP
- Philippines GMP
- Taiwan GMP
- ZAZIBONA GMP

Our Products

Products

Available EU-CTD Dossiers across various therapeutic categories:

- Allergology
- Cardiology
- Central Nervous System
- Dermatology
- Diabetology
- Endocrinology
- Gastroenterology
- Haematology
- Nephrology
- Oncology
- Orthopaedics
- Pathology
- Pulmonology
- Rheumatology
- Urology

For any inquiry please contact us at:
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Our Services

Development

Pharmaceutical development services including turn-key solutions for product realization, from conception to submission. Our competitive advantages include:

Wide formulation expertise ranging from conventional dosage forms to advanced technology platforms:

- QbD based formulation and process development assuring compliance with the current ICH Q8 guideline and trouble-free scale up and technology transfer
- End-to-end product development, including CMO identification and tech transfer activities
- Stand-alone activities such as feasibility studies, troubleshooting (and tech transfer of existing products), consultation and identification of Freedom To Operate (FTO) in cooperation with client's IP Department

Genepharm analytical R&D offers a wide range of services including:

- Development of analytical methods, QbD approach upon request
- Analytical Method validation as per ICH guidelines
- Method transfer procedures to and from external laboratories
- Analytical support of formulation development
- Support of process validation and evaluation activities
- Stability testing in zones I-IV
- IVIVC studies upon request through co-operating parties

Regulatory Affairs

Genepharm team has extensive experience in the regulatory affairs domain within EU and global markets having successfully finalised over 3000 MA sets for its products. Regulatory services offered include evaluation of scientific and technical data and guidance through development, dossier compilation (including eCTD sequences), submission via DCP/MRP, maintenance of marketing authorizations within EU (renewals, variations), liaison with competent authorities and keeping abreast of relevant legislation.

Excellence

Our Production

The Facilities

The company has two state-of-the-art production facilities located in Athens, Greece, designed in accordance with EU cGMP requirements:

Oncology/High Potent Oral Solid Dosage Forms (inaugurated in 2007)

- Product Form: tablets (uncoated or coated) & hard gelatin capsules
- Molecules handled: Anastrozole, Bicalutamide, Exemestane, Finasteride, Fingolimod, Gefitinib, Hydroxyurea, Letrozole, Tamoxifen, Thioguanine
- Granulation Capacity: up to 150 kg
- Primary Packaging: blisters
- Full Capacity: 130 million tablets, 10 million capsules
- Accreditations: EU GMP, Gulf Countries Council (GCC), Health Canada, Therapeutic Goods Administration (TGA - Australia)
- Anvisa accreditation

Conventional Solid Dosage Forms (renovated in 2005)

- Product Forms: tablets (uncoated, coated, oral dispersible and chewable), hard gelatin capsules
- Molecules handled: more than thirty-five (35)
- Primary Packaging: blisters
- Full Capacity: 590 million tablets, 40 million capsules
- Accreditations: EU GMP, Gulf Countries Council (GCC), Health Canada Anvisa, EAEU, and more

Our Activities

Greece

Direct sales & marketing of own branded generics, with a leading position in Greece and continuous growth, covering healthcare professionals in various therapeutic areas.

Around the Globe

- Experienced Management Team in the areas of Formulation & Analytical Development, Intellectual Property, Regulatory Affairs, Manufacturing, Supply Chain, Quality Assurance and Business Development
- Extensive customer network with over 320 partners in more than 90 countries worldwide
- Regulatory expertise gained by working closely with health authorities around the world
- Out-licensing of its product dossiers, linked to supply agreements from own manufacturing and/or CMO facilities
- More than 2000 MA sets have been obtained in EU and 200 MA sets currently in progress
- 760 valid Marketing Approval sets in Rest of the World, another 350 on-going
- Over 1000 agreements for its products with major generic companies
- Sales and Distribution of own branded products in Africa, Asia, Balkans, the Middle East and LatAm

Our Mission

From 1971 to today, Genepharm has one goal. To produce quality generic medicines that meet the needs of patients and contribute to the preservation of their health. Combining its heritage with progress, Genepharm will continue to add value to human life.

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Care

genepharm

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