



Galenika a.d.

67 Years of Leadership in Pharmacy

A Journey of Continuous Improvement

September 2012

GALENIKA A.D. IS...

The only Serbian state-owned pharmaceutical company

Manufacturer of generic drugs – its manufacturing technologies are result of in-house development and long-term cooperation with licensing and contract manufacturing partners (*Hoffmann-La Roche, Abbott, Sanofi* and others)

Company with 67-year-long track record of success established in ex-Yugoslavia

Belgrade based company with close to 2,500 highly skilled, professional and educated staff of all degrees

Market leader in Serbia with strong regional presence and international recognition

Committed to R&D, new product investments and technical innovations



GALENIKA'S MISSION, VISION & GOALS

Our mission is to improve people's health and their quality of life

With the vision to improve the health of all individuals in need – our products allow people to feel better, live longer and lead healthier lifestyles

We continuously strive to improve the quality of our products with the aim of setting best practice standards in pharmaceuticals manufacturing and thereby retain our position of market leadership

Our goal is to invent, develop and improve medicines to prevent disease and improve treatments for supporting healthy lifestyles

We are a corporately responsible and ethical pharmaceuticals manufacturer working to the benefit of our customers, partners, employees and wider society



GALENIKA'S PRODUCTS

Galenika is a manufacturer of generic medicines.

We have a portfolio of over 250 products, medicines from almost all pharmacological groups, dietary supplements, medical devices, dental and common use products.

HUMAN MEDICINES are the largest group within Galenika's portfolio. We cover 13 ATC groups with various pharmaceutical forms, dosages and packagings.

PARAPHARMACEUTICALS portfolio has three groups of preparations intended for prevention and self-therapy – dietary supplements, medical dressings and common use products.

DENTAL PRODUCTS - Galenika is the only manufacturer of products in Serbia for all fields of dental medicine – restorative materials, materials used in endodontics and prosthetics, and fluoride preparations used in prevention and therapy of caries.

RAW MATERIALS are produced primarily for in-house use and domestic industry sectors. Galenika performs biosynthesis of organically-bound oligoelements, and we developed our own industrial biotechnological procedure for production of original probiotic developed by Galenika's research team.



GALENIKA'S BRANDS



In continual development and modernization of Galenika's product portfolio, and in cooperation with licensing partners, while responding to healthcare professional's and citizen's needs, Galenika manages a diverse range of well known medicinal brands prescribed on daily bases.



GALENIKA'S SOLID DOSAGE FORMS PLANT

Brand new, GMP compliant, 10,000 m2 manufacturing facility - annual capacity:
2 BILLION TABLETS AND 100 MILLION CAPSULES (space provided for 25% increase)

Dosage forms: 1. Tablets (coated, uncoated, bi-layered and controlled release tablets)
 2. Hard capsules

Technologies offered:

Blending of powder	Film coating (aqueous, organic, immediate release and delayed release coatings)
Granulation (aqueous, organic)	Sugar coating
Fluid bed drying	Capsulation in hard gelatin capsules
Single-pot granulation and drying	Processing of moisture-sensitive materials (under specific climatic conditions)
Tableting (including double-layer tablets and wide range of tablet shapes and sizes)	Temperature and humidity controlled process rooms and bulk storage

Packaging capabilities:

Blister and strip packs (PVC/PVDC/PP/COC/Aclar/ALU-ALU foils)

Glass or plastic bottles

Carton boxes (secondary packaging)



GALENIKA'S CAPACITIES

Apart from the new Solid Dosage Forms Plant, manufacturing is also being organized in the following plants:

1. Drug Plant – Zemun
2. Parapharmaceutical Plant – Zemun
3. Dental Products Plant – Belgrade
4. Pharmaceutical Raw Materials Plant – Zemun
5. Cephalosporin Plant, Galenika Montenegro – Podgorica

The entire drug production is organized according to pharmaceutical forms:

- Tablets (film tablets and coated tablets)
- Capsules
- Medicinal Ointments, Creams, Gels and Suppositories
- Antibiotics (oral suspensions and capsules)
- Syrups
- Ampoules and Solutions

GALENIKA'S CAPACITIES

Manufacturing is performed in controlled environmental conditions on organized line automated equipment managed by computer systems.

Annual production:

- 2 billion tablets
- 150 million capsules
- 42 million units of sterile preparations
- 8 million bottles of syrups and powders for oral suspensions
- 17 million medicinal ointments and preparations for local application
- 2.2 million instant granulates and powders
- 3 million dressings
- 2.9 million dental products

GALENIKA'S EXPORT

We export 21% of our total turnover to over 20 markets in Europe, Africa and Asia:

1. group: ex-Yugoslav countries (leading export markets), including EU member Slovenia
2. group: CIS countries, including Russia, Uzbekistan, Belarus, Ukraine, Kazakhstan, Armenia, Moldova and Georgia
3. group: African and Asian countries, especially Libya, Yemen, Nigeria, Azerbaijan, Mongolia and Congo

We have representative offices in:

Bosnia & Herzegovina – Sarajevo
Macedonia – Skopje
Romania – Bucharest
Russia – Moscow

We have subsidiaries in:

Montenegro – Podgorica
Bosnia & Herzegovina (Republic of Srpska) – Banja Luka

Distribution and licensing activities are focused on regaining market share in the Russian Federation, and entering the markets of North Africa, Gulf Cooperation Council and central Asia (Turkmenistan, Kyrgyzstan, Tajikistan).



GALENIKA'S QUALITY

CERTIFICATES:

- GMP certificate - issued by the Ministry of Health of the Republic of Serbia (Ukrainian audit, PIC/S member, scheduled for end of 2012; EU audit scheduled for Q1 2013 for obtaining EU GMP certificate)
- ISO 9001:2008 – for integrated quality system - issued by TÜV SÜD
- EN ISO 13485:2003/AC:2007 and EC certificate according to MDD 93/42/EC and 2007/47/EC for medical devices (CE mark) - issued by TÜV SÜD
- HACCP- system for dietary products - issued by TÜV SÜD

All pharmaceutical forms are manufactured in strict compliance with GMP requirements

Quality Control ensures that all starting materials, packaging materials and finished products are of excellent quality prior to release



GALENIKA'S R&D INSTITUTE

The Galenika has its own R&D Institute that develops added-value generic medicinal products, characterized by high levels of safety, quality and efficiency in patient treatment. Galenika's scientific experts are engaged in updating our portfolio, extending the therapeutic coverage of our products, and applying new pharmaceutical technologies to manufacture quality products

The key activities of the R&D Institute are:

- Development of dosage formulations (solid, liquid, semi-solid) including forms with modified release of active substances
- Technology transfer
- Development, implementation and validation of analytical methods
- Scale-up and optimization of technological procedures
- Biosynthesis of new pharmacologically active substances (Probiogal – new probiotic product that is result of in-house development)
- Biocompatibility testing of medical devices, preparation of marketing authorization dossiers
- Project management

GALENIKA'S OPPORTUNITIES

STATE-OF-THE-ART, GMP COMPLIANT PLANT IN EUROPE

- 2 billion tablets and 100 million capsules annual capacity

DUTY FREE EXPORT TO 350 MILLION PEOPLE MARKET

- Preferential trade agreements

<i>Bilateral</i>	<i>Multilateral</i>
Russian Federation Belarus Kazakhstan Turkey Negotiations with Ukraine in progress	CEFTA (Central European Free Trade Agreement) – Albania, Bosnia and Herzegovina, Croatia, Macedonia, Moldova, Montenegro, UNMIK-Kosovo EU – candidate country

RELIABLE THERAPY AT ACCEPTABLE PRICES PROVIDED BY PEOPLE WHO KNOW HOW TO MAKE QUALITY DRUGS

- Competitive prices
- Lower input costs
- Professional and educated experts
- Trained manufacturing staff





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