

Pharmaceutical Industry Overview*

by Raiffeisen Capital & Investment

Romanian health care system • Local pharmaceutical market

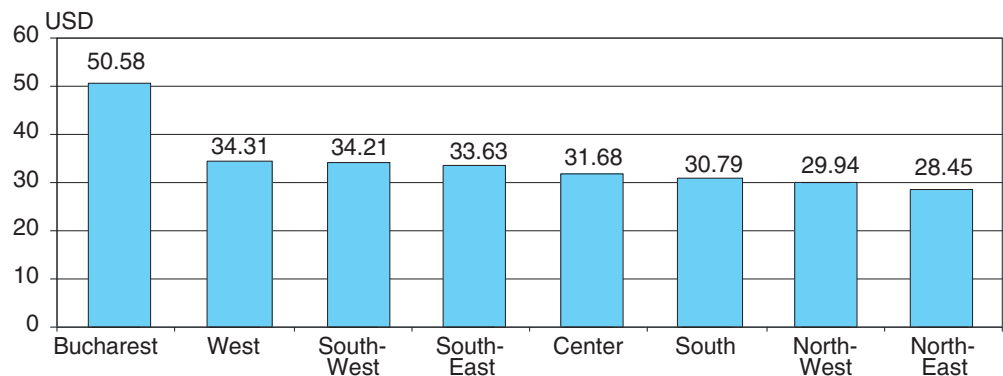
Romanian health care system

Since 1990, public expenditures on health have been below average, even in CEE terms, which affected maintenance, investment in new equipment and access to services, especially for low-income groups.

Currently, the impact of competition in health service provision is not significant. Under-the-table payments are common practice, especially in hospital-based services. Other characteristics include inadequate supply of drugs, lack of good equipment and inequity in health care provision between different social groups and regions. Though slowly, changes are taking place in the system, several private clinics have opened and are well received by the middle and upper income population, while recently the first private hospital opened its doors to the public.

Regional differences within Romania in per capita spending on health care remain significant, ranging from around 170% of the average in Bucharest, to as low as 50% elsewhere. Despite the low level of drug use (only 8-10% of the expenditure of other East European countries) the proportion of drug expenditure at around 20% of total health expenditure is high due to the prices determined by the international market. The graph below illustrates well the gap between Bucharest and the rest of the country:

Spending on pharmaceuticals in Romanian regions (USD per capita)



Financing and reform

Since the mid-1990s, a number of laws have sought to create a more pluralistic and decentralized system. The 1997 Law on Social Insurance attempted to introduce a contractual relationship between health insurance funds as purchasers and health care providers. Prior to 1998, health care was mainly financed by government revenues received from direct and indirect taxes, but also from local government budgets, from the National Health Insurance Fund and from external sources. The Health Insurance Scheme, introduced in 1998, is based on a social health insurance fund. The employer's contribution to the health-care fund is 7% of the gross payroll, while employee's contribution is 6.5% of the gross salary, down from a previous 7%. This is not expected to cover all health care in the short run, and the State will still provide for fundamental needs of the system. Emergency Ordinance No. 150/2002 has replaced Law No. 145/1997.

The new ordinance has created the National Social and Health Insurance Fund, a special purpose fund to be administered by the National House of Health Insurance (CNAS). It defines

* Note: For the purpose of this report, we have used the following sources of information: Statistics yearbook of the National Institute of Statistics; National Medicines Agency (ANM); Pythia International; Sicomed; Antibiotice; Terapia.

with higher precision the institutions, the obligations and tasks, as well as the management of the CNAS budgets. 96% of the CNAS budgets are utilized for the payment of medical services, drugs, sanitary materials and medical tools, to the benefit of insured persons. In turn, the Emergency Ordinance No. 150 /2002 has been modified by Law No. 583/2004. The political objectives of health care reform have been to decentralize the system and create competition among providers. However, given the overall limitation of resources, the prospects for extensive privatization are still limited.

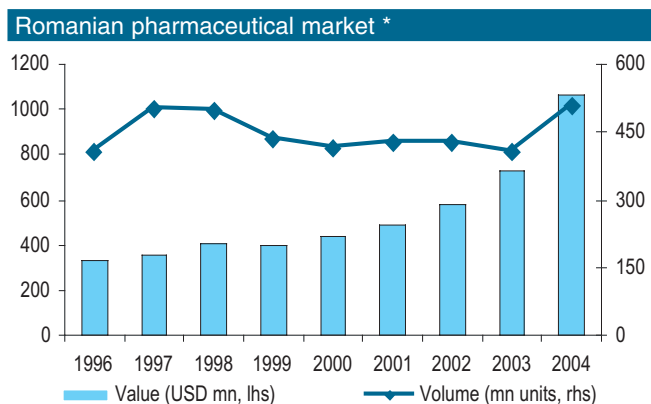
Local pharmaceutical market

During the communist period, the sector was designed to almost entirely satisfy the domestic health-care needs, with only small imports from the former COMECON countries. Though with a broad portfolio, each producer had to specialize in manufacturing certain pharmaceuticals in order to avoid duplication and, hence, competition. Located in different cities, producers were all under centralized management, with the coordination center established at Sicomed. Similarly, R&D activities were concentrated under the Institute for Chemical and Pharmaceutical Research (ICCF) having sites in Bucharest, Iași and Cluj.

After 1990, when foreign trade was liberalized, foreign producers started to show interest for the high growth potential of Romania, a country with a 22 mn population and low drug consumption/capita. They entered the market through direct imports, licensing-in agreements, acquisitions (SmithKline Beecham acquired a 65% stake in Europharm; Lek acquired 90% of PharmaTech; Zentiva took over Sicomed) and privatizations (Gedeon Richter bought majority stake in Armedica).

Pharmaceutical market in figures

Between 2000 and 2004, Romanian pharmaceutical market turnover grew at a CAGR of 24.5% in USD terms, reaching USD 1057 mn in 2004 (ex-manufacturer prices). The market was up 45% y-o-y in 2004 in USD terms, but we note that some of this growth is due to the effect of a weakening dollar. In volume terms the pharmaceutical market went up by 17% in 2004, following a 4% decline the previous year.



Source: Pharmaceutical companies, Raiffeisen estimates
* Market value at ex-manufacturer prices

Every year, the Ministry of Health (MoH) and the National House for Health Care Insurance (CNAS), based on recommendations from the College of Physicians and the

College of Pharmacists, compile a list with prescription drugs that are covered by health insurance funds. The list contains generic substances on which the reference price system is applied and of which part (65% or 50%, depending whether it is the physician's first or second option) of the reference price is reimbursed.

The reference prices are based on the lowest-priced product within a cluster of medicines, as opposed to reimbursing all the medicines containing a certain generic substance regardless of the producer (or price) before. This effectively drives patients into lower priced drugs (mostly produced by local companies) and somewhat limits the growth of the pharmaceutical market.

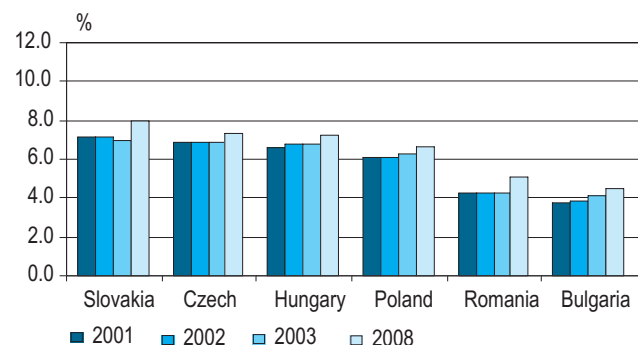
Throughout the post-communist era, payment arrears from CNAS represented a major problem of the Romanian health care sector. Beginning in 2004, an improvement has been experienced in the payment pattern from hospitals while historical debt has also been gradually paid.

LT prospective

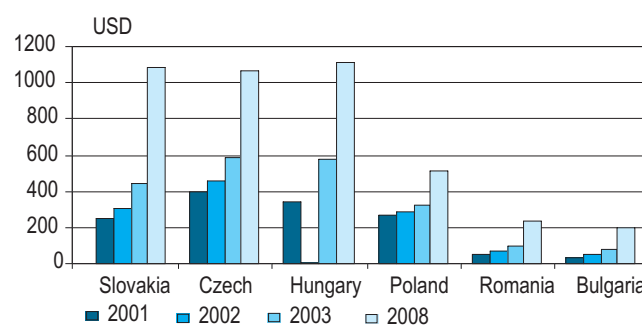
For the medium and long run we believe that the market has the potential to grow significantly as Romania, with a population of 22 mn, is the second-largest country in the CEE area after Poland and it is involved in the EU accession process, having received an accession road map and a target accession date (2007). Even in the unlikely event of the actual accession being delayed, the convergence process would still take place and would be clearly be reflected in the health care sector as well.

The graphs below show Romania's present situation by comparison to the CEE region and point to a great growth potential in the near future.

Comparative healthcare spending as % of GDP



Comparative healthcare spending per capita



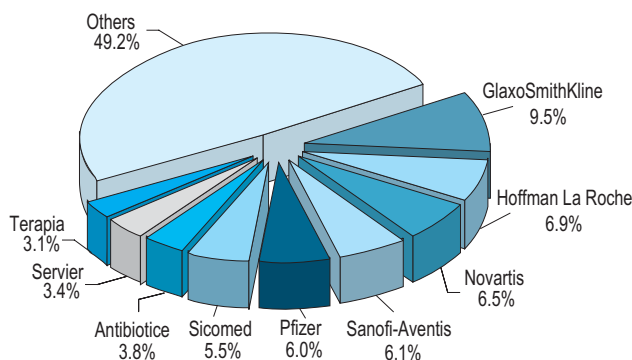
Improved living standards resulting from sustained economic growth, a more efficient system through the introduction of

private health insurance and increased public funding should drive the sector's growth. The low basis formed by the current health expenditure levels (both public and total) augments the growth potential for the Romanian pharmaceutical market.

Main industry players

According to September 2005 data, the market leader is GlaxoSmithKline, together with its Romanian subsidiary, Europharm, with a 9.5% market share. Hoffman La Roche trails at 6.9%, followed closely by Novartis at 6.5% and Sanofi-Aventis with 6.1%. Local producer Sicomed ranks fifth with a market share of 5.5%. Two other local producers, Antibiotice and Terapia, claim a market share of 3.8% and 3.1% respectively.

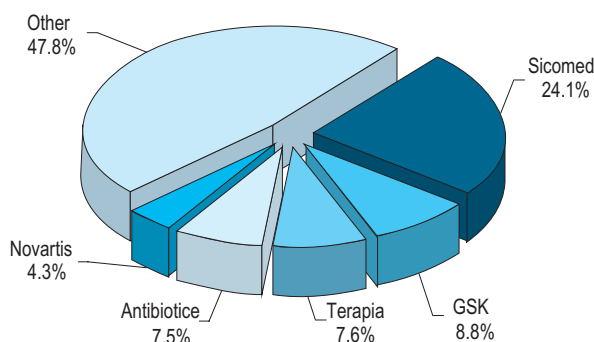
Pharmaceutical market shares (Value, Sept 2005)



Source: Pharmaceutical companies, RCI estimates

In terms of units sold, Sicomed dominates the market (September-2005 figures), with a market share of 24.1%. Sicomed, along with the other local producers, is one of the main beneficiaries of the new legislation, which states that reimbursement should be made on the lowest-priced product with the same active ingredient. GlaxoSmithKline places second with an 8.7% slice, followed by Terapia and Antibiotice with around 7.5%.

Pharmaceutical market shares (Units, Sept 2005)



Source: Pharmaceutical companies, RCI estimates

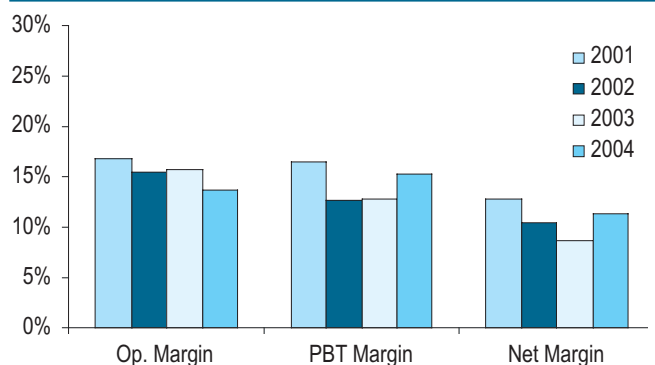
Among the three major Romanian producers Sicomed Bucuresti, and Antibiotice Iasi are listed on the Bucharest Stock Exchange while Terapia Cluj Napoca was de-listed in the last part of 2003, following its takeover by investment fund Advent. In the following section we provide an overview of these local producers.

Brief presentation of the top three traditional producers

Zentiva SA (formerly Sicomed SA)

Established in 1962 as a coordination centre for the pharmaceutical sector, Sicomed is the largest domestic drug producer with a market share of 25% by volume and 5% by value at mid-2005. Initially designed for both primary and secondary processing, the company ceased primary manufacturing activities after 1990, due to high production costs resulting from the use of obsolete equipment. The company currently produces a wide range of human drugs in all major therapeutic groups. Although most of the drugs are generics, the company also produces some patented products. In January of 2006, the Extraordinary General Shareholders' Meeting approved changing the company's name to Zentiva SA, following the recent takeover by Zentiva NV of the Czech Republic.

Profitability evolution



Source: Sicomed, RCI research

The primary production of Sicomed is human drugs. With a large and inefficient portfolio of over 400 formulations in 1990, the company started trimming its product range, eliminating small scale, unprofitable drugs. Currently Sicomed portfolio consists of some 100 drugs in around 200 formulations, but there is still enough room for rationalization, given the company's size. Sicomed's brands are well known in the country and its pricing is competitive in comparison to imported equivalents and other domestic drugs. While introducing new products to fill gaps in the portfolio, the management intends to retain the older products as long as they are relevant to the market and they are able to generate cash.

In 2004, Sicomed became the first Romanian pharmaceutical company to obtain the ISO 9000 and ISO 9001 certificates for its Quality Management System. The next step in its natural evolution, the company later obtained the ISO 14001 (environment management system) and ISO 18001 OHSAS (labor security management system). The above certificates are proof positive of the company's commitment to modern business values and its vision for the future. Sicomed has received GMP (good manufacturing practice) status for all its production facilities.

In June 2005, Sicomed launched on the Romanian market the first five products of the Gerovital cosmetics range, in what is said to be a pilot program for subsequent development of the extremely popular range of products in the United States or Japan. The sales target for the Romanian market in 2005 for the new range of Gerovital products is of about USD 1.1 mn, accounting for 0.6% of the year's turnover. The Gerovital brand, developed in the first

half of the 20th century by Ana Aslan is currently divided between several companies which have rights for pharmaceutical products. At present, the cosmetics range Gerovital Line includes five products (for memory, joints, eyes, heart and menopause), with three additional items to be produced by year-end.

Ownership

The company was listed on the BSE in August 1998. Following the closing of the privatization process in 1999, Venoma Holdings Limited, an investment vehicle, became Sicomed's main shareholder.

At that time, Venoma's shareholders were:

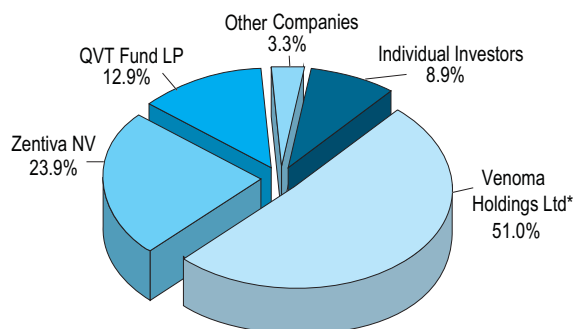
- GED Capital Development representing the European Bank for Reconstruction and Development, GED Eastern Fund and Romanian Post Privatization Fund;
- Global Finance representing Euromerchant Balkan Fund and Black Sea Fund;
- Galenica North East.

At a later time, Galenica North-East sold its stake to the other shareholders, such that GED Capital Development and Global Finance ended up with equal participations in Venoma Holdings.

In October 2005, Zentiva NV, an important regional pharmaceutical player based in the Czech Republic, acquired Venoma Holdings Ltd, thus taking over the majority stake in Sicomed. Following this move, Zentiva launched a Public Tender Offer (PTO) to acquire the remaining shares off the market, with the intention of de-listing the stock.

Following all of the changes described above, the current shareholder structure is presented in the chart below. Please note that, at this time, Zentiva does not hold the necessary stake (95%) to begin de-listing procedures.

Shareholder structure



* - Venoma Holdings Ltd now owned by Zentiva NV

Restructuring program

In 2000 Sicomed started a 5-year investment program aimed at obtaining GMP compliance and raising product and services quality. The company used USD 27 mn until June 2004, for technology upgrades and employees improvement programs. Further on, Sicomed invested over USD 10 mn in rationalizing its production site from 45 hectares to 5 hectares, improving employees' efficiency and upgrading technology in all the main production sections. Also during last year, the company divested its Big Volume Parenteral (BVP) business.

According to Zentiva top management, the acquisition of Sicomed fits into its strategy, to expand into other markets of the CEE region. Zentiva expects this takeover to have a positive impact on cash earnings per share, mostly due to the synergies thus obtained. It anticipates that it would be able to increase Sicomed's operation margins to Zentiva levels within three years.

Sicomed: Summary financials (RAS) in USD mn							
	2000	2001	2002	2003	2004	9M04	9M05
Sales	36.62	36.32	38.58	45.97	53.73	38.89	51.97
Operating profits	7.67	6.01	5.62	6.31	7.05	7.18	13.35
Net profits	8.58	4.56	3.95	3.96	5.97	4.88	11.08
Total assets	40.48	41.51	49.18	61.52	76.86	52.25	106.57
Total equity	33.58	31.83	34.20	39.19	50.65	44.29	62.47

Source: Sicomed, RCI research

Antibiotice SA

Established some 45 years ago in Iași, Antibiotice initially produced active substances to be used by the other domestic producers. In 1990, the company started to invest in secondary processing, which now accounts for the majority of sales. For 2005, preliminary data point to a turnover of USD 56 mn, of which 85% obtained from local sales, with the balance coming from exports. The above results place the company in the top-ten, with a 7.5% market share in terms of units sold and over 3% in terms of value.

Production activities are divided into two main sectors: biosynthesis and semi-synthesis of bulk active substances and production and conditioning of final products under different pharmaceutical forms (suspendable powders, injectables, operculated capsules, tablets, ointments and suppositories). When it comes to finished drugs, the company has a quasi-monopoly position on the domestic market for injectables and has registered an increasing market share for oral solid products.

Antibiotice is the market leader for injectable antibiotics (some 80% market share), as well as ointments and suppositories (90% market share). With a product portfolio consisting of some 180 registered drugs, Antibiotice faces domestic competition on circa 20 products, mainly oral drugs, with Sicomed (now Zentiva) looking like a stronger rival.

Preliminary figures show exports stood at USD 8 mn for 2005 and 25% growth expectations for 2006. In recent times, active substances (Nystatin and Vitamin B12) accounted for circa 85% of total exports. This year, however, the company restructured its export operations, halting exports of Vitamin B12 since it was no longer profitable, while the exports of Nystatin became the focus, since, according to management, it generates solid margins. To further support its export efforts, Antibiotice announced plans to open two new offices in Poland and Hungary.

In 1998, Antibiotice set up its own R&D department focusing on improving existing technologies and introducing new products. The company concentrates its R&D efforts in the following therapeutic classes: anti-infectious, cardiovascular, central nervous system, digestive system, muscular-skeletal system and dermatology. R&D activities materialized in the introduction of new therapeutic forms for pediatric use.

The company has invested to upgrade equipment and production flows to international standards. Following investments of circa USD 45 mn in the last decade,

Antibiotice received the GMP certificate for all divisions and obtained the FDA approval for Vitamin B12 and Nystatin. Part of the reason for the profitability of Nystatin is the recent investment in a new equipment which reduced manufacturing costs for by 40%.

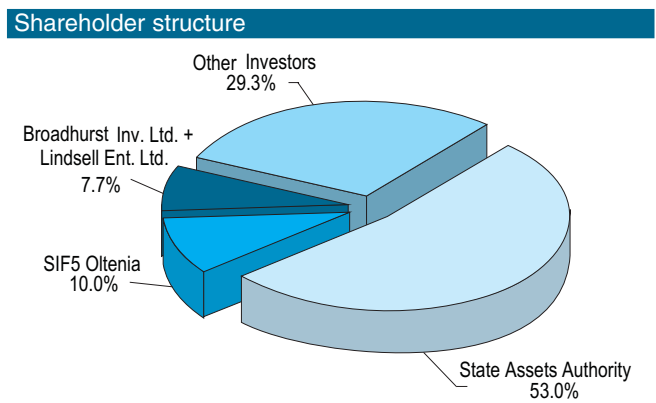
In 2006, ATB plans to invest some USD 3 mn in a new line to increase production of cephalosporin to ten million bottles a year. The management expects the local market of cephalosporin to continue to grow rapidly (it doubled within the last three years), from its current level of 5 million bottles per year, and it also expects to export more. Another USD 1.5 mn is earmarked for an incinerator with a capacity of 250-300 kg per hour. So far, Antibiotice spent more than USD 3.5 mn in environment protection, a must from an EU integration perspective.

To complete its investment program, the company further needs around USD 20 mn over the next five years. The successful implementation of the investment program remains, however, conditional upon privatization (the state still owns a 53.02% stake in the company). Antibiotice was offered for privatization three times so far, to no avail. As a result, in 2003, the company was transferred under the Ministry of Health supervision and its privatization postponed for the time being.

Ownership

The company was listed on the Bucharest Stock Exchange in April 1997. Its majority stake has been under government control ever since, most of this time under the Ministry of Health, having been used as an instrument of control over the price of drugs on the domestic market.

The current shareholder structure is reflected by the graph below.



In July 2005, the government decided to transfer the MoH stake back under the state assets authority (AVAS) control, a first step in the new privatization process. Press reports show that ATB has developed a business and investment plan for the 2005-2013 period in order to obtain EUR 10 mn investment financing from EBRD. This plan sets the investment level at EUR 16 mn, out of which EUR 6 mn would be internal sources, with EBRD providing the rest. The funds are targeted towards new production capacities and the environment.

As the EU integration draws ever closer, the company's privatization grows in urgency. All recent management efforts reflect the emphasis placed on that issue, of which we outline some aspects below.

In the second part of 2004, ATB management introduced the Management by Objectives (MBO) system, which, according to company executives has led to an increase in profitability. The company also intends to expand its portfolio with other types of drugs, for the cardiovascular and central nervous systems.

During last year, Antibiotice started a process of building a new corporate image, another step in preparation for the expected privatization. A new logo, new product packaging as well as a media campaign are on the way.

Antibiotice: Summary financials (RAS) in USD mn							
	2000	2001	2002	2003	2004	9M04	9M05
Sales	28.70	31.34	32.76	36.60	41.70	28.51	40.18
Operating profits	5.69	3.79	5.48	5.52	5.61	5.24	8.22
Net profits	2.18	2.06	3.43	3.57	4.29	2.90	5.90
Total assets	32.44	35.13	43.32	53.55	64.38	50.38	67.08
Total equity	20.25	23.56	25.92	31.78	39.58	32.79	45.20

Source: Antibiotice, RCI research

Terapia SA

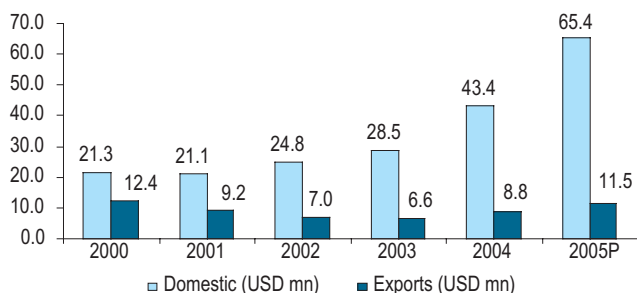
Founded in Cluj-Napoca in 1921, Terapia is a top-ten domestic drug producer, with a market share of 7.5% in volume terms and some 3.1% in value terms. Following acquisitions of Pharmaplant and Promedic last year, Terapia became Terapia Group.

The group's portfolio contains over 150 drugs, both prescription and OTC. Terapia Group exports 25 drugs, most importantly Faringosept - exported to Russia, Ukraine and Poland.

Terapia exports its products to 15 European countries and CIS members and has foreign branches in Russia and Ukraine, employing 28 people in these countries. Of the total of sales registered by the group last year, the drugs for cardiovascular diseases accounted for 45%, drugs for nervous system diseases represented 15% while the products for muscular-skeletal system contributed 12%. Last year the best-selling OTC products were Paduden, Aspacardin, Faringosept, Artroflex, Aspenter. Also last year Terapia's export volume grew by 31% yoy, reaching USD 11.5 mn. Out of the total, generics represent the majority of human drugs, but there are also non-generic drugs produced under co-operation agreements with well-known foreign producers.

A quick look at the recent history shows us that in 2002, Terapia submitted documentation for the registration of 41 products (including food supplements) in 16 countries (former CIS members, but also Hungary, Poland and the Czech Republic). In addition, the company opened a representative office in Moscow and Ukraine (important markets for Terapia's main export driver: Faringosept). Steps forward were also made in 2003, when the company filed the registration documentation for other 11 products. In 2004, Terapia sold some 11% of its output on the Russian market; next, the company turned its attention to the Polish market, by aggressively promoting Faringosept, a well sold product elsewhere, including Russia.

The company's persistent efforts to increase its output are well illustrated by the graph below, with domestic sales posting a robust growth and exports improving steadily.



Terapia’s medium term operating strategy focuses on product portfolio rationalization and reallocation of sales and marketing support towards products offering higher margins. To support sales growth, Terapia built up a team of medical reps to cover the main cities in Romania and increased marketing activities.

Terapia Cluj was the first domestic manufacturer to achieve GMP certification for pharmaceutical production in Romania (1999) as a result of an intensive upgrading process, which consisted of a complete re-engineering of the plant and the implementation of a modern Quality Assurance System.

In 2003, Terapia Cluj also achieved GLP (Good Laboratory Practice) certification for the analytical unit of its clinical and bioequivalence manufacturing center. In 2004, Terapia obtained the renewal of the GMP certification for the pharmaceutical production of solid tablets.

In 2005, Terapia acquired Bucharest-based pharmaceutical companies Pharmaplant and Promedic, thus extending its products portfolio while aiming for a 15% increase in market share. The two companies have a combined turnover of over USD 6 mn and they employ more than 100 people. Promedic is a joint Romanian-French venture set up in 1992, while Pharmaplant, set up in 1997, was running on privately owned Romanian capital, producing liquid generic drugs.

For 2006, Terapia plans USD 10 mn investments in a new warehouse and a building for packaging its products. Furthermore, according to its management, the company plans to launch new products from four therapeutic areas, while focusing on exports in its key markets.

Ownership

In 1996, the company had been privatized through the mass privatization process, after which, the following year, it listed on the stock exchange. In the summer of 2003, Terapia changed its shareholders structure: Terapia Holding (wholly owned by a consortium including Advent International and EBRD, among others) acquired a 90.7% stake in Terapia (for an estimated USD 40 mn). Following a mandatory tender offer, the company was de-listed from the Bucharest Stock Exchange in March of 2004.

Most recently, media reports indicate that buyout talks are taking place between Terapia ownership and several

potential strategic investors. Such reports are not surprising, since the current majority owner is a financial investor, aiming to maximize the return on its investment in a set time. Two other factors combine to support the imminent takeover hypothesis: there are relatively few independent producers left in the region; Terapia has gone through a restructuring process, making it more attractive to investors.

Distribution and retail

Manufacturers and wholesalers concentrate most of the distribution operations in Romania. Generally, distributors are also importers of foreign made drugs.

The table at the bottom of this page shows a breakdown of Romanian pharmaceutical market in 2002, 2003 and 2004. Sales to hospitals represented 30.4% of the market in 2004, slightly up from 29.2% in 2003, but coming closer to the 32.6% in 2002. Sales to pharmacies stood at USD 681.5 mn in 2004, up 32.7% y-o-y. The weight of prescription drugs in overall sales to pharmacies remained around the 75% level throughout this time.

A glance at the historical breakdown between the sales channels (i.e. pharmacies and hospitals) shows that the retail segment is driving the industry growth. The poor status of the health care system does not allow for a marked growth in the hospital segment, mainly subsidized by the budget.

Main players – distribution

The distribution market is currently highly fragmented with top five distributors sharing slightly above 50% of the market and close to 30 other companies competing for the rest. It is likely that a consolidation will take place in the following years under various pressures including suppliers, competition or legal.

Mediplus, part of A&D Pharma, is the market leader; its operations are based on a network of 12 warehouses and a storage capacity of over 10,000 sqm. Europharm is part of GSK group and operates a network of 16 warehouses. Relad Group includes two companies specialized in import and distribution of pharmaceuticals, Relad International and Relad Pharma. The Group operates 16 warehouses (one central and 15 local) and has a customer base of 3,000 pharmacies and 400 hospitals. Another major presence on the retail market, Fildas conducts its distribution operations through a network of 16 warehouses.

Main players - retail

Pharmacies and pharmacists were among the first health facilities and professionals that were allowed to operate privately. As a result, most of today’s independent pharmacies were privatized through MBOs and, typically, the former manager is still in charge. Management style, as well

Romanian pharmaceutical market									
	2002			2003			2004		
	USD mn	Weight	Y-o-y Ch	USD mn	Weight	Y-o-y Ch	USD mn	Weight	Y-o-y Ch
Total	577.6	100.0%	13.7%	725.0	100.0%	25.5%	1057.01	100.0%	45.8%
Pharmacies	389.2	67.4%	10.3%	513.4	70.8%	31.9%	751.08	71.1%	46.3%
Rx	294.1	50.9%	10.3%	387.6	53.5%	31.8%	594.52	56.2%	53.4%
OTC	95.1	16.5%	10.2%	125.8	17.4%	32.3%	156.56	14.8%	24.5%
Hospitals	188.4	32.6%	21.5%	211.6	29.2%	12.3%	305.93	28.9%	44.6%

Source: Pharmaceutical companies, RCI estimates

as the services offered, has not changed significantly. There are currently approximately 4,500 outlets in Romania, corresponding to one pharmacy for some 5,000 inhabitants.

The most widely recognized brand is Sensiblu, a pharmacy chain with close to 150 outlets. Sensiblu is part of A&D Pharma, also owning top-ranking distributor Mediplus. Catena, owned by Fildas, enjoys a strong presence with a total of 118 pharmacies. Another well recognized brand is Help Net, a pharmacies chain with some 75 outlets, which is part of the same group with Farmexim, a top-five distributor. Europharm, owned by GSK, has a network of 33 pharmacies, in addition to its wholesale activities.

Due to the high fragmentation in the industry, the number of pharmacy chains is currently small. Most of the pharmacies are independent, but we note that they constitute powerful group that is able, among other, to impose its decisions in the College of Pharmacists.

Framework

The Ministry of Health is the entity responsible for setting up the pricing mechanism of both imported and domestically produced drugs. Prices and margins are subject to tight regulation, which sets maximum levels for the margins allowed to each type of player. For some imported drugs both the end price to the customer and the import price for the product are set.

According to the existing regulations, the producer may adjust the prices of domestic drugs periodically, based on the inflation index and the local currency depreciation. The

Ministry of Health must be notified about any price adjustments. New drugs are priced based on the traditional cost – profit analysis, justifying the proposed costs.

For OTC drugs, margins are not restricted.

The Health Insurance Law provides, among other things, patients' access to reimbursed drugs. Every year, the Ministry of Health and the CNAS compile a list that determines which prescription drugs are covered by health insurance funds. The list is based on recommendations from the College of Physicians and the College of Pharmacists and includes drugs listed as generic compounds. If a doctor indicates the generic name of a prescription, pharmacists must dispense the cheapest drug.

Drug registration

The National Drug Agency (ANM, a public institution subordinated to the Ministry of Health) is the body responsible for the authorization of drug production, import, registration and distribution. The registration process takes on average 12-18 months, being much shorter (circa 3 months) for drugs having the EMEA (European Medicine Evaluation Agency) registration certificate. Drugs have to be re-registered every 5 years and the process can take up to 10 months. The procedure for drug registration is now in line with the EU standards.

The Control Department within the ANM is responsible for monitoring drug quality, inspecting production facilities and issuing the Certificate of Good Manufacturing Practice. The GMP certificate must be renewed every other year.

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