

THE EVOLUTION OF THE ROMANIAN PHARMACEUTICAL MARKET THROUGHOUT THE LAST GREAT RECESSION

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Abstract

As the whole world economy was affected lately by the financial crisis, it was clear that the Romanian pharmaceutical market could not have remained untouched. Even so, this segment of the market is still slowly growing.

Manufacturers are facing great challenges imposed by the often harsh changes in legislation and pharmacies themselves need to constantly adapt to the amendments made to prescription drugs. Large pharmaceutical chains have sometimes flourished in this environment, but some small independent pharmacies vanished.

The Pharmacy Law brought about a much needed regulatory framework in the field, even though certain amendments have had to be made.

Rezumat

În contextul în care întreaga economie globală este afectată de criza financiară actuală, devine evident faptul că piața farmaceutică românească nu poate să rămână neschimbată. Acest segment al pieței este încă într-o dezvoltare moderată.

Producătorii se confruntă cu mari provocări, impuse de modificările adesea severe din legislație, iar farmaciile trebuie să se adapteze în mod constant reglementărilor impuse medicamentelor pe bază de prescripție. Acest fenomen s-a dovedit benefic pentru unele lanțuri farmaceutice, în timp ce multe farmacii independente au falimentat.

Legea Farmaciei a adus un cadru legislativ de mare necesitate în acest domeniu, deși s-au făcut ulterior unele modificări.

Keywords: Romanian pharmaceutical market, Romanian Ministry of Health, pharmacies, manufacturers

Introduction

The Romanian pharmaceutical market functions in the context of a National health insurance program, similar to other European countries. Nevertheless, the business environment lacks three essential qualities: legislation stability, transparency in policymaking and efficient communication with stakeholders. These drawbacks come on a background of chronic underfunding by the Government for healthcare in general and

where the absence or poor quality of preventive and primary care worsens general public health creates a demand for treatment that cannot be tendered [1,2].

The Romanian Pharmaceutical Market at the Beginning of the Great Recession

Key Market Factors in 2008

In 2008, for the first time during the previous years, the general opinion on the progress of the Romanian pharmaceutical market was pessimistic. That was due to the local players' financial results after the new regulatory decisions, and even more because of the general financial clutter.

The optimism of the recent years regarding the potential of the Romanian pharmaceutical industry and the enthusiastic forecasts reflecting a double digit market growth were already being replaced by a more grim perspective for the following years.

Before Cegedim's release of the final data for 2008, the unstable market environment created uncertainties concerning the sector's growth rate for the whole year, mostly due to the amplified burst of the local pharmaceutical crisis in October and the late influence of the global financial crisis on the local economy, in the last quarter of 2008.

According to Cegedim, the total pharmaceutical market value in 2008 was around EUR 1.95 bn (RON 7.16 bn), showing an increase of 6.6% y/y in EUR terms and approximately 18% y/y in RON terms. That is how the double digit increase of the sales in the pharmaceutical sector represented a pleasant surprise, indicating that the market managed to recover in December, posting a 23% y/y in Q4 2008 [3,4].

Nonetheless, there was a decline of 2.3% in the number of pharmaceutical units sold in 2008 as compared to 2007. The explanation was that the sector's increase in value was related to either a raise in the OTC drugs prices at the entrance on the market of new and more expensive molecules, whether they were originals or branded generics.

During the second half of the year, the interest of international players for acquisitions in the local pharmaceutical market dropped due to problems they were facing on their home markets. Several deals were thus delayed or at least put on hold because of the global financial crisis. Local media reported a potential sale of *Ozone Laboratories* and also the prospective sale of a leading retail chain to an international strategic investor. The intention to resume the privatization of *Antibiotice Iasi, Romania* in September or October 2008 was not implemented due to the expected elections in November and to the low evolution of the company's share price on the Bucharest stock exchange. In February 2009, the

company's market capitalization was of EUR 40 mn, down by almost 80% as compared to the previous year [5].

Regulations

A great influence on the development of the pharmaceutical market had the local currency depreciation and the ever widening gap between the evolution of the RON/EUR exchange rate and the fixed rate used to calculate the regulated prices for the Rx drugs. Both wholesalers' and retailers' profit margins were badly affected, as the former reduced discounts granted to the latter or refused to continue delivering drugs below the acquisition price. The loss became even greater as the Ministry of Health repeatedly postponed the decision to update the prices. The crisis culminated at the beginning of October with the distributors' protests and their decision to stop the delivery of drugs in pharmacies, bringing a direct impact on the producers' annual balance sheet. Luckily, consumers were not so greatly affected due to the existing pharmacy stocks.

At the end of October 2008, the Ministry of Health was forced to find a temporary solution and update the exchange rate used to calculate the drugs prices from 3.32 RON/EUR to 3.6 RON/EUR. The agreement was in place until the end of December 2008 only for imported medicines, but this decision was not reflected in the final prices as the distribution mark-up was diminished for some products [2,9].

The use of an exchange rate of 3.6 RON/EUR was then extended until the end of January 2009, due to the parliamentary elections and the appointment of a new Minister of Health. In the meantime, the exchange rate exceeded 4.2 RON/EUR, causing even more losses to the distributors. The losses from the currency depreciation surpassed 30% since the wholesalers were trying to collect the money for the products sold 6 months before, at an exchange rate of 3.2 RON/EUR. Eventually, the authorities adopted a new resolution, applicable starting 1st of February, to upward readjust the prices for Rx drugs, using an annual fixed exchange rate of 4RON/EUR. The distribution mark-up was unified both for imported drugs, as for the local produced drugs, but for medicines with prices more than RON 200, the mark-up was fixed to RON 20.

On the other hand, in an attempt to stimulate sales, the Ministry of Health suspended the pharmacy ceiling for the reimbursed drugs starting October 2008. Some distributors announced that the measure had lead to an increase in demand by at least 30% in the last quarter of the year. Previously, the pharmacies had been under a monthly reimbursement cap imposed by the Ministry of Health, which was insufficient and which was used up rapidly in the first half of the month.

The Pharmacy Law (no. 266/2008) was finally approved and published in the Official Gazette no. 765/13 in November 2008 and was enforced 60 days after the publishing date. Romania had previously been the only country in the European Union without a pharmacy law. The sector had been regulated partially by a number of decisions issued by the Ministry of Health and partially by an older law, stipulating a series of reforms on the Romanian healthcare system.

In April 2008, the regulatory authorities shifted from INN to brand prescription rule. This decision favored the large companies with considerable marketing budgets to promote their drugs to physicians, the main decision making factor. That is how expensive originals and well-known branded generics increased their market share, while cheaper unbranded generics or less-known branded generics were disadvantaged. But because of the often changes in the prescription rules, most of the local companies tried to adapt by developing a mixed portfolio, of both branded and unbranded products or by sustaining an umbrella brand, which was easier and cheaper to promote than individual brand names [9,12,13].

Leading pharmaceutical manufacturers in 2008

In 2008, the top three market leaders of the pharmaceutical industry interchanged their positions. The local entity of the English drug producer GlaxoSmithKline, which had been the lead for the previous ten years, was surpassed by the Swiss rival Hoffmann La Roche. Beginning with the second quarter of the year, GSK also lost the second position in favour of the French group Sanofi-Aventis. Top local producers were Terapia Ranbaxy, Zentiva, Antibiotice, Actavis, Gedeon Richter Romania SA, Labormed and Biofarm.

Pharmaceutical Market Evolution in 2009

An inflection point was reached in 2009 when, although the market had been forecasted to increase in RON, it suffered a decrease of approximately 2.0% in EUR due to a strong depreciation of the national currency.

13 pharmaceutical companies, GSK, Zentiva, Actavis, Terapia Ranbaxy, Pfizer, Eli Lilly, AstraZeneca, Abbott, Bayer, Ozone, Antibiotice, A&D Pharma and Sensiblu changed their executives in 2009. Their decisions came in a time when the shareholders were increasing the pressure to obtain positive financial results. 2009 also registered a record level of the executives in the pharma industry leaving their positions. For the first time, there were executives with three mandates in a year or companies which changed more than two executives in a year.

Moreover, in October 2009, payment deadlines were extended from 60 days to 210 days for reimbursed drugs covered exclusively by CNAS and from 30 days to 120 days for drugs covered by the National Health Programmes.

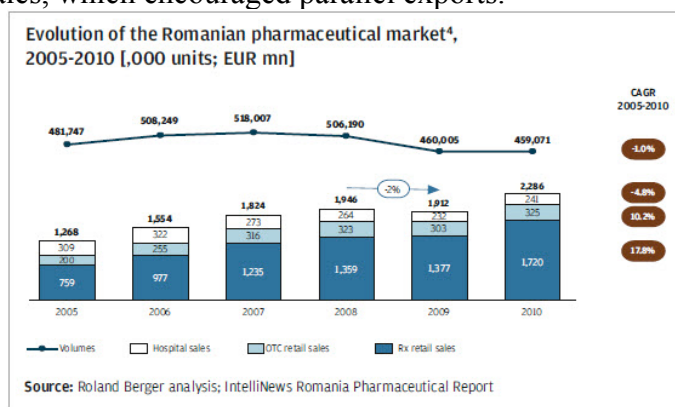
Another regulation that affected the market was the introduction of the claw-back tax. It said that manufacturers were supposed to pay a quarterly contribution to the Ministry of Health according to the sales of Rx drugs, sales to hospitals and within the National Health Programmes. The tax rate was determined based on the total quarterly Rx sale and ranged from 5-11%.

The Romanian claw-back tax is clearly tougher on the market players, compared to similar taxes from the EU because it does not include the following clauses, fundamental for the correct functioning of the tax in countries like the Netherlands and the UK [8, 9, 10,12]:

- It should only be applied to a reference base, the tax being levied on the marginal increase in sales against the reference base
- It should have as computational base the production price, in order to avoid taxing the margin
- It should be exclusively applied on public spending for compensated drugs, after the patient's contribution is taken out
- It should not be applied to generic drugs because their presence on the market directly generates reductions in the drug expenditure

Moving on to 2010

In 2010, the pharmaceutical market recorded a rebound, growing by 19.6% against 2009, amounting to around EUR 2.3 bn. This positive evolution occurred in spite of the slight decrease (-0.2%) in volumes sold. The reasons for this were probably the diminished public support in the acquisition of prescription medicines and the negative margins registered for domestic sales, which encouraged parallel exports.



Pharmaceutical Market Structure

The two distribution channels in the pharmaceutical market, hospital and retail, represent disproportionate fractions of the market. Retail was then covering 90% of the market in terms of value and almost 95% in terms of volumes.

Retail had been the main driver for market growth over the previous years, with 2010 increases in value of 21.7% and in volume of 0.8%. The development was attributed to a price surge in the prescription drug area and to the complete or partial transfer of drugs pertaining to several National Health Programs from hospital to retail pharmacies. This was the case for oral anti-diabetics and insulines, post-transplant, HIV and oncology drugs.

Also, hospital pharmacies were greatly affected by poor management and financial blockages in the system, as reflected by the massive 14.1% decrease in volume and by the slight 4.3% increase in value.

Rx drugs held a market share of around 84% of retail sales in value terms. Prescription sales were led by antibiotics and alimentary tract remedies. On the other hand, OTC drugs lost market share to Rx drugs and reached a level of EUR 0.32 bn in 2010. Product groups with the highest sales were those for treating cold and flu (14% market share), analgesics (13% of the market) and vitamins and minerals (11% of the OTC market).

Original drugs represented about 73.2% of the market in terms of value and approximately 25.0% in terms of volume, with eight of the top ten producer companies by sales being R&D based.

Almost all therapeutic areas registered double-digit growth during the period June 2009-June 2010, with cardiovascular medicines being the largest segment on the Romanian pharmaceutical market, followed by antineoplasics and immunomodulating agents, alimentary tract and metabolism, central nervous system and anti-infective systemic drugs.

According to the Cegedim report, Sanofi-Aventis ranked first on the market, with sales of around EUR 210 mn. Hoffman la Roche came second, followed by Pfizer. Novartis ranked fourth, followed by GlaxoSmithKline. Following up were the French company Servier, the American company Merck&co and the British group AstraZeneca.

Local production covered only 30% of the market value, with Zentiva, Antibiotice, Actavis, Labormed, Ozone Laboratories and Biofarm being the biggest local players.

Regulatory Framework

The Ministry of Health set the levels of maximum commercial mark-ups for pharmacies 12.0-24.0% (maximum RON 35/EUR 8), distribution at 7.5% and additional import services at maximum 8.5%.

Furthermore, the Ministry of Health updated the price establishing methodology through Norm no. 220 from 12.03.2010, with the redefinition of the calculation method of the maximum admissible prices for drugs. The producer price was set as the average price out of the three lowest prices that the drug is sold for, among the 12 reference European countries (Czech Republic, Bulgaria, Hungary, Poland, Slovakia, Austria, Belgium, Italy, Lithuania, Spain, Greece and Germany). Additionally, drug prices were adjusted according to the conversion rate EUR-RON used in 2011 budget calculations, set at 4.21 RON/EUR and in force as of April 2011. The update also increased the relative price limit for a generic prescription drug from 65% to 70% of the price of the equivalent original drug.

As to prescribing, in July 2010 the system changed from the brand name to the active substance in a certain therapeutic class, expecting to determine a slowdown in the pharmaceutical market growth, as it favored lower priced drugs.

Regarding retail pharmacies, the exception according to which an additional pharmacy could have been opened in train/bus stations and airports, as well as in commercial centres with a selling area of more than 3,000 sqm, surpassing the demographic criteria, was abrogated in December 2010. This was a consequence of the already high number of pharmacies functioning in these locations.

In November 2010, the Government approved changes to the Health Reform Law no. 95/2006, by including the copayment system in a revision of Article 190. This system was supposed to provide a new source of financing. Under this scheme, patients' copayment fees would be on a scaled basis, ranging from EUR 1.20 for a consultation with a general practitioner, EUR 2.20 for one day spent in hospital to EUR 50 for an MRI scan. Patients would pay a maximum of EUR 140 per year in copayment fees. These fees were expected to generate revenues of EUR 89 mn per year. The funds would be collected and retained by the healthcare provider. Private healthcare providers would have no restrictions, but public providers would be required to invest the funds in medical service. To date, measures have not been implemented [5, 6, 7, 13].

Projections for the Future

The Business Monitor International estimated the Romanian pharmaceutical market at 6.0% for 2011. By 2015, BMI forecasts that pharmaceutical sales will reach RON 17.03 bn, achieving a five year compound annual growth rate of 7.4% in local currency terms. Real GDP growth is estimated at 2.5%. These estimations are based on the gloomy outlook for Romanian exports on account of the recession in the eurozone.

Domestic demand should nonetheless remain supportive of economic expansion over the quarters ahead.

Conclusions

Despite extremely difficult conditions for pharmaceutical companies, the Romanian market is growing, even in the context of the global economic decline.

The retail pharmacy segment clearly outpaces the hospital pharmacy market and, as predicted, prescription drugs outgrow OTC medicines.

The leading pharmaceutical manufacturers sometimes interchange their positions, but the first five generally remain Sanofi, Hoffman la Roche, Novartis, Pfizer and GlaxoSmithKline.

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