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PHARMACEUTICAL INDUSTRY IN ROMANIA

EMBASSY OF INDIA, BUCHAREST

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Pharmaceutical according to Western concepts may seemed to many, in the early 90's in Romania, a simple fad. If you were trying to describe a pharmacy then, you couldn't help but notice the small counter you were leaning against, the "sour" workers and the pronounced smell of disinfectant. Immediately after 1990, many pharmacists took over the locations where they had been active before the Revolution. Distribution companies took over the market and took over the connection between the drug manufacturers and the pharmacies where they were sold.

In the retail area, the market was extremely fragmented, the concentration trend starting to manifest itself after 1995, but the pace was quite low: in 2004, out of 3,800 pharmacies operating in Romania only about 10% were part of a big pharmacy chain. However, regional pharmacy networks have developed, some of them are currently in the process of expanding nationwide and in the present, they took over almost completely over the small pharma businesses. Three out of ten national pharmacies belong to one of the top five players in terms of number of units, after large networks added about 200 new units in the last five years as a result of market transactions.

In Romania, 22 factories have stood the test of time and are now trying to impose themselves on a market that is heading for 3 billion Euros and which is dominated by international giants.

The two oldest factories, Terapia and Biofarm, have a history of 92 years, the second going through a nationalization. Most of the pill production units are owned by international groups, with only one producer, Antibiotice Iasi, being controlled by the state through the Ministry of Health.

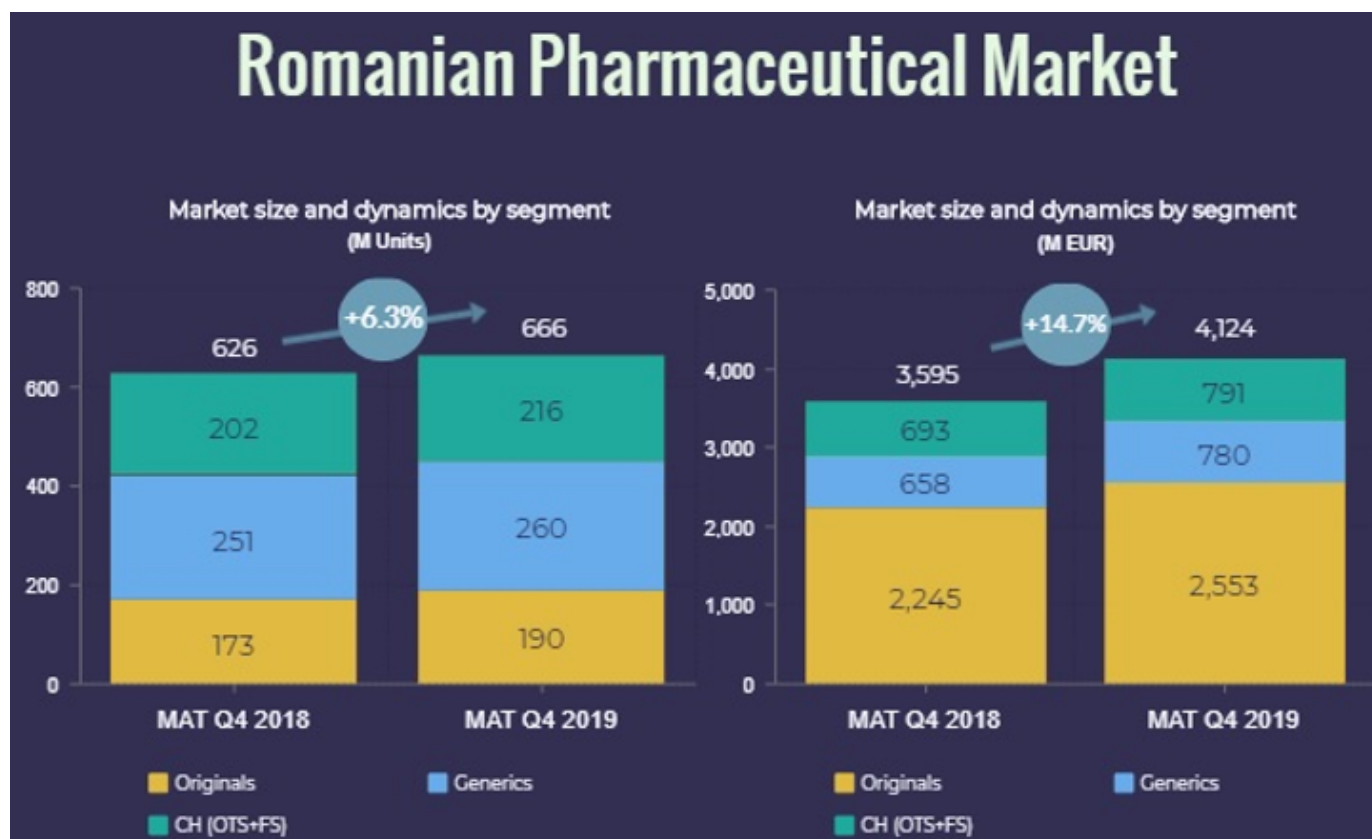
Stakeholders across the entire healthcare spectrum in the country – from government to industry to patient, associations to healthcare professionals – have enumerated the various challenges facing the Romanian healthcare ecosystem. Inadequate public investment at half the level of the European average to a crippling and exceptional ‘clawback tax’ imposed on the pharmaceutical industry that effectively compels the industry to subsidize one out of every four patients in the public health system. The lengthy and unpredictable clinical trial and drug approval timelines that complicate patient access to new innovations.

The value of medicines delivered to patients in Romania was 17.98 billion Lei at the distribution price, 6.2% more than in April 2018 - March 2019. Also, in the same period, the total volume of drug consumption was 641.4 million boxes, increasing by 3.2%.

In the first quarter of 2020, the total volume of medicines released to patients amounted to 179.1 million boxes, an increase of 9.7% compared to the first quarter of 2019. The increase was generated by both the retail channel (10.0%) and to a lesser extent, by the hospital channel (3.0%). By segments, volume growth rates were 4.7% for Rx in pharmacies and 18.7% for OTC in pharmacies.

In the first quarter of 2020, the total value of medicines released to patients amounted to 4.81 billion Lei, up 3.5% compared to the first quarter of 2019. At the same time, prescription drugs in retail pharmacies were increased of 10.5% compared to the first quarter of 2019. By segments, the growth rates in Lei were -7.1% for prescription drugs, 26.8% for OTC in pharmacies and 19.2% for hospitals.

Romania pharma market growth and dynamics between 2018 and 2019 by segment.



The top local drug distributors are Mediplus Exim SRL, with a turnover of 3.9 billion Lei, followed by Fildas Trading SRL (3.6 billion Lei), Alliance Healthcare SRL, Farmexim SA and Sanofi Romania SRL. Cumulatively, these five companies had a turnover of over 14 billion Lei in 2018, respectively 42% of the total turnover generated by local distributors.

According to KeysFin's report, the turnover in Romania's pharma industry - including production, distribution and retail - will surge by nearly 13% this year in 2020 to RON 67.8 billion (EUR 14.12 bln), as this is one of the industries that thrives during the coronavirus (COVID-19) pandemic period. The average annual growth rate of the industry, over the past nine years, has been 7.2% per annum. There are sectors likely to thrive, such as the pharmaceutical industry, an industry that has grown steadily over the past 10 years and that will probably reach another all-time high this year.



“In 2020, the pharma industry, which is at the forefront of the fight against coronavirus, will contribute both to the stability of the local economy and to the health of Romanians,” said Roxana Popescu, Managing Director of KeysFin.

Medicine shortages have been a growing issue across the European Union, especially for drugs that target serious chronic diseases or cancers. Romania is one of the countries that are most affected by the problem, as a result of its low prices and lack of preventative measures.

The parallel export of medicines has been a hot topic in many EU states in the recent period, as it is often assumed to be one of the primary causes of shortages. Several countries have limited or banned the parallel trade (import/export) of medicines, as EU law states that trade restrictions can be justified on public health grounds.

Vytenis Andriukaitis, the European Commissioner for Health, in a speech in early October has listed the main reasons for shortages are - manufacturing problems; the pharmaceutical industry's heavy reliance on ingredients imported from non-EU countries (80 percent of active ingredient come from China and India); supply management issues such as insufficient supply quotas from the industry and the difficulty in substituting drugs; commercial withdrawals by manufacturers, which mostly affect cheaper and older products.

On September 13, 2020, the Romanian Health Ministry announced a project for a six-month suspension of parallel exports for 172 INNs (International Non-proprietary Names (INN) identifying pharmaceutical substances or active pharmaceutical ingredients), corresponding to over 2,000 products (trade names, pharmaceutical forms, strengths and pack sizes).

The Ministry's project has not yet been approved and the Ministry has not published a final analysis that would highlight the impact of parallel exports on the availability of these drugs and potentially justify the restriction on export.

APMGR, PRIMER: The current method of calculating the clawback tax removes cheap medicines and local manufacturers from the market.

The Association of Manufacturers of Generic Drugs (APMGR) and the Romanian Association of Industrial Drug Manufacturers (PRIMER) accuse the authorities of ignoring the solution of the differentiated calculation of the clawback tax despite the disappearance of thousands of cheap drugs and despite impact studies supporting the validity of this measure.

The differentiated calculation of the clawback tax was validated by impact studies conducted by the National Health Insurance House (CNAS). CNAS considered a viable solution, which would reduce the clawback tax for cheap drugs to 18.57% in the fourth quarter of this year, compared to the level of 27.53% estimated by CNAS in the situation where the current method of calculating the tax remains unchanged.

For expensive medicines, the impact is only 1%, and the impact on fund raising from the state budget would be negligible, of about 7,000 lei per month, it is shown in a press release published by APMGR and PRIMER.

Top 50 Pharma Companies in Romania Ranking

Among top 50 pharma companies in Romania, by value, Multinationals MSD, Sanofi and Novartis top the list for the year ending December 2019. However, regional players such as Romanian firm Antibiotice, Slovenian Krka and Czech-head quartered Zentiva are also represented.

The local Pharma industry in Romania has 22 factories, concentrated in nine cities, most of them in Bucharest and Targu Mures, according to data from the Association of Generic Drug Manufacturers in Romania (APMGR). Thus in Bucharest companies like Biofarm, Zentiva, Labormed, Actavis, Laropharm, Infomed Fluids, Sintofarm and SlaviaPharma are located, while in Târgu Mureş Gedeon Richter, Bioeel, Sandoz and Vim Spectrum are located.

Indian pharma companies such as SunPharma, Dr. Reddy's Labs, Sunwave Pharma and Prime Healthcare are present in Romania.

Some important facts about Pharmaceutical industry of Romania:

(i) Total imports of Pharmaceutical products by Romania from other countries: 3.83 Billion USD (2019)

(ii) Total exports of Pharmaceutical products by Romania to other countries: 928.65 Million USD (2019)

(i) Major items of import: medicament mixtures put in dosage, human and animal blood, pharmaceutical preparations, dressing packaged for medical use.

(ii) Major items of export: tablets, liquid substances for oral administration i.e. syrups, internal solutions, also topical preparations, lotions, gels, sprays.



Details of pharma associations, investment promotion agencies, key Ministries etc.

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