

CBI MARKET SURVEY

THE PHARMACEUTICAL PRODUCTS MARKET IN ROMANIA

Publication date: February, 2010

Introduction

This CBI market survey gives exporters in developing countries information on some main developments in the pharmaceutical products market in Romania. The information is complementary to the information provided in the CBI market survey 'The pharmaceutical products market in the EU', which covers the EU in general. That survey also contains an overview and explanation of the selected products dealt with, some general remarks on the statistics used, as well as information on other available documents for this sector. It can be downloaded from <http://www.cbi.eu/marketinfo>.

1 Market description: consumption and production

Data concerning consumption and production of pharmaceutical products in Romania are derived from the European Federation of Pharmaceutical Industries and Associations (EFPIA). The latest report from this organisation (The Pharmaceutical Industry in Figures, 2009 Edition) provides data as of 2007. Data for previous years are derived from previous editions of this report. Please note that data for both consumption and production of pharmaceutical products are given at ex-factory prices.

Consumption

Romania was the seventeenth largest pharmaceutical market in the EU in 2007, which amounted to € 1.6 billion. The country accounted for 1.1% of the EU pharmaceutical market (about the same size as the Czech pharmaceutical market). In comparison, France and Germany, the largest pharmaceutical markets in the EU, individually accounted for 18% of the EU market. Between 2005 and 2007 (data for other years are not available), Romanian consumption of pharmaceutical products increased by an annual average rate of 22%, which was much higher than the increase for total EU pharmaceutical consumption, which grew by an annual rate of 6.7% during the same period.

Please note that data on consumption of specific pharmaceutical products is fragmented and cannot be presented in a structured manner. Additional information can be found under the section 'Trends in consumption'.

Generic medicines

In 2007, Romania's generic medicines market amounted to an estimated € 456 million. Approximately 29% of the Romanian pharmaceutical market consisted of generic medicines (at ex-factory prices), comparable to the high level of generic penetration in markets such as Germany. Between 2005 and 2007, Romania's generic medicines market increased at an annual average rate of 16%.

Trends in consumption

- **Market segmentation:** In addition to an increasing consumption of pharmaceutical products in recent years, another characteristic in the Romanian market has been the transfer of oncologics and anti-diabetics from hospital to retail sales (Antibiotice Annual Report, 2007). The liberalisation of some products into the retail market has made it easier for patients to obtain certain pharmaceutical products and has led producers to release new products, in order to gain a larger share on this segment.
- **Cardio-vascular diseases:** According to industry sources, Romania has experienced a strong increase of cardio-vascular diseases in the last few years, which now corresponds to the main cause of mortality in the country. For this reason, consumption of products to combat these afflictions has increased proportionally; cardiovascular products lead pharmaceutical sales in Romania, having a share of 20% with respect to the total market.

- **Non-prescription products:** Some of the most commonly consumed non-prescription pharmaceutical products in Romania are analgesic-antipyretic and antispastic products (Antibiotice Annual Report, 2007). Aids to digestion are also among the top-selling non-prescription products.
- **Non-prescription vs. prescription:** According to RNCOS – Industry Research Solutions (2009), the Romanian pharmaceutical market is faced with rising sales of prescription pharmaceutical products (mostly reimbursable), whereas the non-prescription market remains flat. This reflects the current state of the Romanian market, where consumers have a lower purchasing power, due to the economic crisis, and prices of non-prescription products have increased at significant rates.

For more information on trends in pharmaceutical products, please refer to the CBI survey 'The pharmaceutical products market in the EU'.

Production

In 2007, Romania was the sixteenth largest pharmaceutical producer in the EU, accounting for over 0.2% of total EU production. The largest producer in the EU in 2007 was France, which accounted for 21% of the total production. Between 2005 and 2007, Romanian production increased by an annual average rate of 24%, amounting to € 280 million in the latter year. The increase in Romanian production was well above the EU average of 3.5% during that same period and represents one of the highest growth rates in the EU.

Please note that data concerning the production of specific product groups in Romania are not available.

In addition to its production, Romania's pharmaceutical industry Research and Development in 2007 was estimated at € 30 million, accounting for only about 0.1% of total EU pharmaceutical industry R&D. The UK, which had the leading pharmaceutical industry R&D, accounted for a share of 29% of total EU R&D, closely followed by Germany (20%).

There are approximately 300 manufacturers, importers and distributors of drugs on the Romanian market. It is important to note that Romania's pharmaceutical production is strongly focused on generic medicines.

Some of the leading pharmaceutical companies in Romania are:

- Zentiva (part of Sanofi-Aventis group) - <http://www.zentiva.ro>
- Antibiotice - <http://www.antibiotice.ro> - the leading manufacturer of anti-infectives
- LaborMed Pharma - <http://www.labormedpharma.ro> - the largest private Romanian independent generics producer
- A&D Pharma - <http://www.adpharma.ro>
- Sensiblu - <http://www.sensiblu.com>
- Help Net - <http://www.helpnet.ro>
- Remedio Farmacii SA - <http://www.remedio.ro>

The leading multinational pharmaceutical companies in Romania, in order of market share, are: GlaxoSmithKline, Roche, Sanofi-Aventis, Novartis, Servier and Pfizer.

Trends in production

- **EU requirements:** Before joining the EU, Romania's pharmaceutical industry went through a lengthy process of adaptation to EU requirements, which has raised production standardisation and levelling in relation to its EU counterparts.
- **Export-orientation:** Romania's recent entry to the EU has started to trigger exports in its pharmaceutical industry. Exporters now have easier access to international markets. The domestic company Antibiotice, for instance, has expanded its exports to more than 40 countries.

For more information on trends in pharmaceutical products, please refer to the CBI survey 'The pharmaceutical products market in the EU'.

Opportunities and threats

- +/-Romania's recent entry into the EU is promising, in terms of purchasing power increase and subsequent growth in the consumption of pharmaceutical products. Note, however, that the economic crisis is affecting consumption of pharmaceutical products in the country, especially regarding non-prescription products.
- + Generic medicines dominate the Romanian market, which points toward positive prospects for exporters in developing countries.
- Nonetheless, Romania itself is focused on the production of generic medicines and, in combination with its relatively cheap labour force, Romania represents a potential threat to suppliers in developing countries.

Exporters should take into account that the same trend can be an opportunity for one exporter and a threat to another. Please, review these opportunities and threats according to your own situation. Chapter 7 of the CBI market survey 'The pharmaceutical products market in the EU' presents an example of an analysis of whether a trend/development is an opportunity or a threat.

2 Trade channels for market entry

The trade structure for pharmaceutical products across the EU is mostly similar, but reveals slight variations according to the diverse pharmaceutical and healthcare systems existent in each country. These variations hardly affect an exporter's market approach, since they are related to the way pharmaceutical products are domestically dispensed to the end-consumer. Some of the specific characteristics of the Romanian pharmaceutical trade channels and trends therein are outlined below:

- According to EFPIA, around 78% of pharmaceutical products in Romania is sold through pharmacies and another 22% is used in hospitals (in terms of value). The Association of European Self-Medication Industry (AESGP) further indicates that, in 2008, Romania had approximately **450 wholesalers** and **7,600 pharmacies** (AESGP, 2009).
- Some of Romania's leading pharmaceutical wholesalers are:
 - Mediplus (a member of A&D Pharma) - <http://www.mediplus.ro>
 - Relad Pharma - <http://www.relad.ro>
 - Farmexim - <http://www.farmexim.ro>
 - Polisano - <http://www.polisano.ro>
 - Fildas Group - <http://www.fildas.ro>
- Characteristically, the **leading pharmacy chains** in Romania share ownership with some of the **largest pharmaceutical wholesalers**, such as Sensiblu (held by A&D Pharm) and Help Net (held by Farmexim). The top pharmaceutical retail chains in Romania are: Sensiblu, Catena and Gedeon Richter (Raiffeisen Investment Romania, 2008).
- Neither **distance-selling** nor **self-service** of pharmaceutical products is allowed in Romania (AESGP, 2009).

Please, refer to the CBI survey 'The pharmaceutical products market in the EU' for further information on EU pharmaceutical trade channels.

Price structure

Price decisions in Romania are taken independently from reimbursement decisions. Prices are controlled for all pharmaceutical products, with the exception of non-prescription ones. International price benchmarking is used, and the reference countries are Czech Republic, Bulgaria, Hungary, Poland, Slovakia, Austria, Italy, Lithuania, Denmark, the UK and Germany. Prices are compared at the manufacturing level, and the criteria used is the minimum price in the selected countries.

Prices of pharmaceutical products for human use in Romania may not exceed maximum levels established by the Ministry of Health in its catalogue – <http://www.ms.ro>

Different prices apply throughout the various trade channels. The margins applied to pharmaceutical products in Romania can be expressed in the following manner:

- Wholesaler: 7.5%
- Pharmacist: maximum margin of 24% (depends on the level of the wholesale price)
- State (Value Added Tax - VAT): a reduced VAT of 9% is applicable to pharmaceutical products (the standard VAT rate is 19%)

Prices of imported pharmaceutical products which are not yet marketed in Romania - thus not found in the price catalogue - should be determined according to the certified external DAF price, the Customs exchange rate, the import margin (8.5%), and the commercial margin for the distribution (7.5%) and the VAT rate (9%). Prices for Romanian and imported pharmaceutical products which are certified and may be revised (usually on an annual basis) are considered maximum, and are adjusted according to the catalogue of the Ministry of Health (AESGP, 2007).

For further information on price structure of pharmaceutical products in Romania please refer to AESGP's *Economic and Legal Framework for Non-Prescription Medicines*, which can be purchased at: <http://www.aesgp.be/publications/countryProfiles.asp>.

3 Trade: imports and exports

Imports

In 2008, Romania was the seventeenth largest importer of pharmaceutical products in the EU, accounting for 1.3% of total EU imports. This is quite limited when considering the population size of the country, but probably more reflective of the low average income levels in Romania. Between 2004 and 2008, Romania's imports increased at a strong annual average rate of 25% in value and 21% in volume, amounting to € 1.5 billion or 30 thousand tonnes in 2008. The majority of Romania's imports (86%, in terms of value) was sourced in other EU member countries. Imports from EU countries increased by 27% annually in terms of value between 2004 and 2008. Germany, which accounted for a 17% imports share in 2008, was the leading supplier of pharmaceutical products to Romania, followed by France (13%) and Hungary (13%).

The role of developing countries in supplying pharmaceutical products to Romania is small, but it is significant when compared to other EU countries. In 2008, imports sourced in DCs accounted for 3.8% of Romania's total imports. However, imports from developing countries increased at a lower rate than overall imports, at 11% annually during the review period, indicating a decreased share in imports. India was the main DC supplier, accounting for 2.6% of total Romanian imports in 2008. Moreover, imports from India increased by 36% annually on average in the period under review. Imports from Egypt, the second largest DC supplier, increased by 1.2% annually on average in the same period.

In 2008, Romania's imports of pharmaceutical products consisted of packed pharmaceutical products (99%) and non-packed pharmaceutical products (1%). Developing countries accounted for 2.2% of Romanian imports of non-packed pharmaceuticals.

Exports

Romania is one of the smallest exporters of pharmaceutical products in the EU. In 2008, Romania was the sixth smallest EU exporter, accounting for only 0.1% of total EU exports. Nonetheless, Romania's exports increased by a strong annual average rate of 80% in value and 86% in volume between 2004 and 2008, amounting to € 144 million or 9.5 thousand tonnes in 2008. Approximately one third of Romania's exports was destined for EU countries, around 37% was destined to extra-EU countries (excluding DCs), and another 34% to DCs.

Russia, the leading country of destination, accounted for 30% of Romanian exports, followed by Ukraine (20%).

In 2008, Romania's exports of pharmaceutical products consisted almost entirely of packed pharmaceutical products. Non-packed pharmaceutical products accounted for only 0.4% of the total exports.

Opportunities and threats

- +/-Imports of pharmaceuticals into Romania are low. Although imports increased strongly in the review, they remain limited. Considering the large population and strong economic growth, it can be expected that import growth will continue at a high rate, which could increase the interest of the Romanian market in the long term.
- +/-Although only accounting for 3.8% of total imports, developing countries play a relatively large role in the Romanian pharmaceutical market. However, imports from developing countries are increasing at a lower rate than overall imports, and are heavily dominated by just two countries, India and Egypt.

Exporters should take into account that the same trend can be an opportunity for one exporter and a threat to another. Please, review these opportunities and threats according to your own situation. Chapter 7 of the CBI market survey 'The pharmaceutical products market in the EU' presents an example of an analysis of whether a trend/development is an opportunity or a threat.

Useful sources

- EU Expanding Exports Helpdesk - <http://exporthelp.europa.eu>
- Eurostat – official statistical office of the EU - <http://epp.eurostat.ec.europa.eu>
- Understanding eurostat: Quick guide to easy comext
http://epp.eurostat.ec.europa.eu/newxtweb/assets/User_guide_Easy_Comext_20090513.pdf

4 Price developments

Pricing systems vary in the individual EU countries, thus this is also the case for price developments. The main price developments observed in Romania in recent years are the following:

- The Romanian Ministry of Health aims at reducing the prices of pharmaceutical products at the manufacturer level, by enlarging the number of reference countries with those having the lowest pricing levels. Note that Romania already has one of the lowest pharmaceutical price levels in the EU.

Useful sources

- ITC market news service (MNS) - <http://www.intracen.org>

5 Market access requirements

As a manufacturer in a developing country preparing to access Romania, you should be aware of the market access requirements of your trading partners and the Romanian government. For information on legislative and non-legislative requirements, go to 'Search CBI database' at <http://www.cbi.eu/marketinfo>, select 'pharmaceutical products' and 'Romania' in the category search, click on the search button and click on market access requirements.

Detailed information on packaging can be found at the website of ITC on export packaging: <http://www.intracen.org/ep/packit.htm>

Information on tariffs and quota can be found at <http://exporthelp.europa.eu>

6 Doing business

Information on doing business like approaching potential business partners, building up a relationship, drawing up an offer, handling the contract (methods of payment, and terms of delivery) and cultural differences can be found in CBI's export manuals 'Export Planner', 'Your image builder' and 'Exporting to the EU'. These can be downloaded from <http://www.cbi.eu/marketinfo> - go to search publications. For more information on doing business in Romania, visit the following websites:

Trade associations

- Romanian Association of International Medicines Manufacturers (ARPIM) - <http://www.arpim.ro>

Trade press

- HotNews.ro - <http://english.hotnews.ro> - publishes interesting articles on the pharmaceutical industry from time to time.

Trade fairs

- RomPharma - <http://www.rommedica.ro> - an international exhibition of medicines for human and veterinary applications. The event takes place once a year in Bucharest and the next event is expected to take place in April 2010.

This survey was compiled for CBI by ProFound – Advisers In Development
in collaboration with Jan Ramakers Fine Chemical Consulting Group

Disclaimer CBI market information tools: <http://www.cbi.eu/disclaimer>