Medicines distribution in Romania in the context of global market

ANA-LUCIA RISTEA  
SORIN POP  
ION STEGAROIU  
GABRIEL CROITORU  
Management – Marketing Department,  
Faculty of Economic Sciences, "Valahia" University of Targoviste,  
Lt. Stancu Ion, nr. 35  
ROMANIA  
risteanaalucia46@yahoo.com  
sorin.pop@labormed.eu  
stegaroiuion@yahoo.com  
croitoru_gabriel2005@yahoo.com

Abstract: - The medicine definitions differ from a country to another; finding a certain definition to be appropriate for the analysis from the perspective of the thematic issue of the present paper has become a necessity. As a first defining characteristic, it has to be pointed out that the medicine is not like the other commodities. It is meant for the most intimate human needs, thus affecting the quality of life, welfare, but also malady, death or human being cure (J.P. Buisson şi D. Giorgi, 1997). Consequently, the medicine may be assimilated to a public cvasi-commodity (or under trusteeship), a fact proved by the public authorities attitude which include it into the political or sanitary (D. Richard şi J. L. Senon, 1996) and establish organizations to control the supply and demand of medicines. This definition emphasizes the fact that the medicine offer is under trusteeship and regulated throughout the entire chain of value, at least on five levels: 1. Research (research labs must be in accordance with a certain number of international regulations), 2. Manufacturing (production process must respect the 'Good practices of production), 3. Marketing authorization released by the trusteeship authority, 4. Medicine including into its category of accessibility and 5. Medical staff which becomes the real decision maker with regard to medicine administration. All these regulations imposed internationally and supported by OMS influence considerably the medicine production and distribution. That is why the analysis of medicine distribution on a national market cannot be done without taking into account the international market characteristics. In such perspective, the present paper was structured in three sections: (1) Characteristics of medicines global (2) Organizing the system for distribution of medicine in Romania (3) New challenges of distribution of medicinal in Romania

Key-Words: - Medicine, national sanitary system, medicine distribution

1. Characteristics of medicines global

1.1 New challenges in the supply of drugs  
Supply of drugs also had to adapt a backup of patent law and a profound technological revolution that transformed the research methods of medicines.  
A. Agreements relating to intellectual property rights issues affecting trade (ADPIC), signed in 1994 by WHO, have set a common minimum level of intellectual protection rules, but enforcement mechanisms and penalties that each State must be included in the law (and B. Coria., 2006). These agreements have greatly changed the pharmaceuticals market. In developed countries, they have strengthened and expanded the existing protection system, while for countries where no legislation exists, ADPIC led to the establishment of a protection system for a wide range of products which were not provided before. The patent system gives companies a monopoly to the extent that each new molecule receive a certificate with a validity period of twenty years, this can be extended by a supplementary protection certificate for a maximum of five years. Patent law began in the 1980s, and since 2000 has produced the effect v the first patent expiry - the progressive loss of monopoly rents for such companies holding brevets. The most significant decreases were recorded turnover drugs classified as "blockbusters" (drugs whose turnover exceeds a billion dollars). These losses are due to
progressively replacing the generic category of ethical drugs ("textbook").

B. The transition from technologies created by the chemical industry to develop new technologies based on biotechnology, since the 1960s brings into question the principle of chemotherapy demonstrating that chemistry is not the only therapeutic procedure or only source of innovation. Thus the average number of medicines made from molecular biology (bio-medicines), the total number of molecules in the development worldwide has increased between 2004 and 2006 from 18% to 25% (Ph. Coutinet, Abecassis and Nathalie, 2008 p.114). Widespread introduction of biotechnology in the drug industry needs knowledge increases, the savoir-faire and technology required to develop new molecules. But no single company fails to fully master the technology research: innovation is strongly linked to the scientific activities and relationships that firms may have with research institutions (Ph. Coutinet, Abecassis and Nathalie, 2008, p.114). Correlated with prolonged phases of research and development, these new technologies have generated large increases in the cost of developing a drug: on average, to 318 million dollars in 1987 to 802 million dollars in 2003 (J. Dimas al., 2003, pp.151-185).

C. The drug industry has had to fold the sanitary requirements of increasingly stringent, which were translated by a strengthening of procedures for marketing authorization of medicines. A new molecule, to claim such a permit must undergo a process of development strictly regulated and conducted in four successive phases: first there are three clinical phases, the latter phase of pharmacy co-vigilance. One consequence of these regulations is an increase in the cost and duration of access to the market.

1.2 The new requirements demand
The application of drugs in the world has experienced significant changes that have affected the profits of pharmaceutical companies forcing them to alter their strategies. Thus, the major challenges facing the drug industry must be reported behavior changes are caused by two great actors of the application: 1) the patient and 2) national health systems (Ph. Coutinet, Abecassis and Nathalie, 2008, pp.116-119).

1) The patient became better informed and more active. Once the early 1990s, users of health care in general and medicine in particular, have a greater amount of information, accessible and increasingly accurate. The main vector which ensures that extension of coverage of pertinent and relevant information required by patients is the Internet. Multiplying the medical system, maintained by pharmaceutical companies, public power, but also associations of patients or patients themselves, show a genuine mature behavior. Information gained from the web sites, becoming more precise and more focused on supply and demand of drugs, allowing patients to better understand disease and health system, while helping to change their behavior in front of eye care. A second source of information is the patients' associations. Created mostly by doctors, health professionals or pharmaceutical companies to support and inform patients, these associations, bringing together the main users of health care systems, aimed at informing patients or their families about the disease and his treatments.

2) National health care systems, to higher costs related to both aging and new drug price increases have strengthened their control spending. The difficulties of financing social protection leading actors in Western countries healthcare systems to better manage health costs. The drugs are often the largest chapter of the insurance costs of the disease and their share continues to grow. Measures arising here are related to the procedures for negotiating price, determining reimbursement rates (price compensation), and controlled, directly or indirectly - through the development of generic and OTC medicines - sales volumes.

1.3 A complete renewal strategies of pharmaceutical companies
Developments related to the global drug market, presented in previous sections of the essay, have affected the strategies of firms operating in this market, both in terms of organization and choice of product. Thus, firms have developed, on the one hand, industrial strategy gradually leading to the emergence of a "new model" for pharmaceutical companies and, on the other hand, more direct marketing strategies focused on patients (Abecassis and Nathalie Coutinet Ph., 2008, pp .122-133).

1.3.1 New industrial strategy
Transformation of industrial organization that led to a new model for pharmaceutical companies resulting in a threefold process:
I. A process of disintegration and centering.
In early 1970, activities were held in the bosom of pharmaceutical chemical industries. Large pharmaceutical companies were integrated and performing the activities of chemistry, pharmacy and agrochemicals. In the early 1990s, these large vertically integrated groups began a phase of
disintegration, and thus transfer some of their activities. So for example, in 1993, the British group ICI has split its operations between chemistry (ICI) and pharmacy (Zeneca). If many firms have split their activities (aiming at separation of the pharmacy and Agro-chemistry), these operations have been accompanied by transfer of fusion operations. In the early 2000s, this process of transfer-merger occurred and led to a centering of activities and a strong specialization of firms in certain therapeutic classes or certain stages of production, particularly research and development. AstraZeneca Group is an example in this direction centering.

Refocusing it on ethical drugs ("textbook") led to the disposal activities were not part of the core of his job (and specialty products division dental anesthetic). The group is now specialized in certain therapeutic classes such as major cardio-vascular system, central nervous system, and anti-cancer (Ph. Coutinet Abecassis and Nathalie, 2008, p. 123).

II. An increase in industry concentration. In the 1990s, the pharmaceutical sector is marked by a wave of mergers and acquisitions on a scale that has never met before, a phenomenon that has led to a strong increase in the concentration of activity in the drug industry. This process of increasing the concentration of the pharmaceutical industry has created large-sized companies and global market presence. Table 1 shows data for example the largest mergers and acquisitions that have occurred since 1996.

III. An outsourcing certain activities. Specialization process described above is accompanied by a significant move by companies to outsource some of their traditional activities. This process began for research - development (especially development) today touches all phases of manufacturing, distribution. Research and development phase is composed of research and development activities. The development phase has undergone numerous changes that have led to increasing complexity of activities they require. Three dimensions explain this trend: the increasing number of trials required to obtain a permit, increasing the number of patients on whom these clinical trials are conducted and the number of tests performed on each patient (Abecassis and Nathalie Coutinet Ph., 2008, p. 127).

Or to deal with that increases the complexity of development activities, pharmaceutical companies, faced with the concerns of their research approaches, are convinced that outsourcing is the appropriate development of certain molecules.

2. Organizing the system for distribution of medicine in Romania

2.1 The legal framework for the organization of production and product distribution on the Romanian market

Drug/medicine market, whether it's production or it's distribution, is the nearest open market. Drug market is found for monopoly elements (certain drugs are offered by a single vendor), and the oligopoly. Because of the implications of their specific traits that economic good product (underlined in the first paper), is an intense regulated market. In the process of convergence of the Romanian market operation mechanisms with the mechanisms developed and strengthened over time, the EU market, and promoted in Romania were the fundamental laws governing the production and distribution of drugs, namely:

- Law nr.336/2002
- Law 95/2006 on healthcare reform on the drugs used to address special needs;
- Law nr.266/2008 pharmacy;

In accordance with the Law nr.336/2002, the medicinal product means "any substance, mixture of natural substances or products manufactured, sold, offered for sale or used in the treatment, mitigation, prevention or diagnosis of diseases" (art. 2).

The Law on medicinal products for human use is not only defines what is meant by drug, but drug use (types of drugs, reactions to medications, a label and distribution, risks caused etc.). Manufacture of medicines is done by manufacturers who have obtained approval from the MSP operation. Producers who apply for authorization must have its own laboratories quality control of packaging and raw materials that can perform process control and finished product control. Operation is required to obtain proof of competence in the field. Thus, the person responsible for the production activity must have:
- Bachelor degree in pharmacy;
- Bachelor degree in chemical engineering, chemistry and bioengineering;
- Bachelor degree in medicine or biology.

In addition, it required proof that these persons have at least two years of work in a production unit authorized medicinal products in the field.

The new regulations were laid down both production and distribution of medicines, and other
categories of products such as herbal medicines, homeopathic products and food supplements to meet the needs and the harmonization of Romanian legislation with EU legislation. Regarding the authorization of the manufacture and distribution of drugs, it is done by the National Agency for Medicines (also active observer of the European Medicines Agency), taking into account the type of product, as follows:

- category of ethical drugs for medicinal products (reference), in order to permit laboratory tests are needed and clinical trials;
- For generic drugs, these tests are not required.

Exception from approval by the National Agency of Medicines are drugs to be approved by the European Medicines Agency (regulation 726/2004) and radiopharmaceuticals prepared in pharmacies when using. Distribution of the product lies in its transfer from producer to final consumer. Unlike other sectors of the distribution in the field of medicinal products is a clear distinction between the distribution of wholesale and retail, each of the two types with specific regulations.

Medicines deposits are authorized by the MoH, they function by performing specific operations, wholesale only, with products that are included in its own approved list MSP. It is forbidden to retail direct store.

Deposits must be specialized personnel (pharmacists, physicians), to dispose of properly equipped facilities and the entire activity shall be conducted in accordance with good distribution practice.

Retail drug distribution is done through a network of pharmacies. All drugs sold through pharmacies must have a marketing authorization, authorization granted by the National Agency of Medicines. Meanwhile, the National Medicines Agency determines the classification of medicines into two groups:

- Group A, the prescription to the pharmacist that the prescription (recipe), with different arrangements: valid for six months (the patient stays), prescription retained in pharmacy, special prescription, restrictive recipe (for drugs that can be used in special areas);
- Group B, related to drugs obtained without prescription.

Medicines are distributed by:

- open circuit network pharmacies (independent), to pay or offset system drugs;
- hospitals, where access to drugs is, at least theoretically, free to the patient, hospital, medicines are purchased by auction (currently held electronically via the Internet) and paid with money from the district health insurance houses (CHIH);
- ambulatory care sector, where different rules apply: For a list of drugs for serious diseases, patient access is guaranteed and the financing is provided by the national health programs, for other operations, there is a list of drugs that apply the system of reference prices, affordable in 70% of CHIH, PANS difference to 100% being paid by the patient for the remaining drugs (other than those included in the lists mentioned above), full payment is made by the patient.

2.2 Romanian drug distribution market dynamics

From the outset it should be noted that the evolution of the Romanian market the product is part of the global pharmaceutical market trends, economic environment caused by mutations triggered by a complex of factors influence commensurate hard against the background of the globalization of markets generalization (these aspects are by the first statement of the doctoral student).

According to Cegedim Romania, published in Business online Pharma, the Romanian pharmaceutical market tendencies and know the same world market, thus remarked:

- Upward growth over the past three years, turnover, and more on the retail market (25%), reduced by the circuit hospital (1.2%). According to forecasts Cegedim pharmaceutical market will grow further, with percentages ranging between 5 and 15%. In 2010, the Romanian pharmaceutical market will reach a level of maturity, at the threshold of 3 billion euro, which corresponds to the consumption of drugs per capita of 138 euro (from July 2006–June 2007, consumption was 1 8 billion euro, respectively 83 euro per capital).

- Market pharmacies (retail market) accounts for 82% of the total pharmaceutical market, representing 18% of the hospital market. Reduction trend is continued, the hospital market share, company Cegedim's estimates, the ratio will stabilize somewhere around 90% and 10% market pharmacies hospital market (this proportion is found that the trend in EU countries). The market share of pharmacies is always justified the upward trend and the number of pharmacies: from a total of 1948 pharmacies in 1990 to 6127 pharmacies in 2008.

- Such trends are manifested in other EU countries, and stands on the Romanian market makers tend to "jump" over wholesalers and distributors to supply directly to customers - hospitals and pharmacies. According to studies, 18% of the total
pharmaceutical market in volume, is the distribution channel directly (bypassing the wholesale distributors).
• In these circumstances, it finds an intense phenomenon of concentration of deposits. In Romania there are about 200 registered companies are active in the distribution of drugs. Of these 10 companies accounts for 80% of drug distribution.

3. New challenges of distribution of medicinal in Romania
The new challenges of the drug market in Romania should be considered in the overall process of national health system reform, both as a complex process initiated internal necessity but also as a requirement of convergence with EU practices in the field.

3.1 Several arguments justifying health reform
Ministry of Public Health (MPH) aims to improve the health of the population and achieve a modern and efficient health system, compatible with European Union health systems, being permanently in the service of citizens. This vocation of the MSP is implemented and by pursuing the objectives set by the strategic plan.
In exercising its powers, MSP collaborates with both international bodies (World Health Organization, European institutions, the World Bank, Global Fund, etc.) And central public administration authorities and local public institutions in the country specialized, professional organizations (College of Physicians in Romania, the College of Pharmacists of Romania Order of Nurses and Midwives in Romania), with business at home and abroad, legally constituted associations of patients in private and civil society in general.
Latest version of the strategic plan developed by the MSP, for 2008-2010, sets out a package of courses of action that will be presented in summary in this section of the essay.
External environment analysis highlights a range of opportunities and threats that should be considered in implementing the MSP strategy. Thus, I noted the following opportunities and threats:
■ Opportunities
• The health sector is a major social impact, which can provide arguments for the adoption of policies.
• EU membership requires the adoption of standards and recommendations that were at the improvement of efficiency and quality.
• EU membership opens new possibilities for financing projects from EU funds.
• Interest of local government authorities to take some of the responsibilities of Public Health.
■ Threats
• Increasing awareness of patient progress and diversification along with diagnostic and therapeutic technologies will increase their expectations and hence to an increase in demand for medical SERVICING complex health system must have mechanisms to ensure targeting of resources. The principle of financial efficiency.
• Freedom of movement of persons and services enables users to make contact with service providers in different countries and to change their expectations.
• Development of the private system is a competitive environment for the public.
• Free movement of persons and facilities created after Romania's accession to European Union employment job risk induce migration specialist staff, especially the highly skilled and efficient.
• An aging population and young workforce migration.
• Increased costs induced by either side cover treatment of rare but very serious, either because policies practiced by some drug dealers.
• Lack of specific training in health in the local government level.

3.2 Development trends on the Romanian market drug distribution
Among the strategic axes of the Ministry of Public Health Strategic Plan for 2008-2010 also include the improvement of drug distribution on the Romanian market. For this strategic axis to set the overall objective of designing the list of essential medicines for public health, to be covered totally/partially by social health insurance system.
In accordance with Government Decision no. 1841/2006 for approving the list of common international names for medicinal products benefiting policyholders in outpatient treatment, with or without a personal contribution, the prescription, the health insurance system, insured persons may be relevant to a number of prescribed drugs Common names 1036 International (DCI). Of these, 119 drugs that meet the DCI may be paid compensation at 90% of the reference price, 148 drugs that meet the DCI may be paid compensation at 50% of the reference price. Also receive appropriate medications a DCI 275 v 100% clearing rate of the reference price v children aged 0-18 years, young people from 18 years to 26 years if enrolled in education, and also pregnant women.
Implementation of Directive 89/105/EEC on the transparency of measures regulating the prices of medicines for human use and their inclusion in national health systems, implemented in the Health Minister Order no. 612/2006 Norms regarding the calculation of prices of medicines for human use as amended and supplemented, Ministry of Public Health provided the legal framework for establishing a uniform and transparent pricing, which allows the classification of settlement funds allocated to prescription drugs.

The overall objective that is subject to a number of specific objectives, including:

a) ensuring adequate stocks of drugs in pharmaceutical establishments;
b) affordable by developing appropriate standards of prices for medicines for human use, together with representatives of manufacturers and distributors of medicines and professional organizations - the College of Pharmacists in Romania, Romania College of Physicians and Pharmacists Employers' representatives, the Ministry of Health Public review of regulations to reduce the prices of their drugs;
c) continuing professional education of pharmacists and pharmacy assistants;
d) verifying the implementation of pharmaceutical legislation, namely the application of regulations issued by the Ministry of Public Health.

f) the establishment of pharmacies, pharmacy outlets authorized by the Ministry of Public Health in disadvantaged areas;
f) allocation of adequate funds by the health insurance houses to settle the drug released.
g) to provide the support required for entry into the country, storage and distribution units, replacement medication approved by the Ministry of Public Health in the existing treatment centers under the Ministry, and the centers established by the NAA (National Agency Against drug).

4. Conclusion

The new industrial strategies of the medicine are overlapped marketing strategies that aim both at practitioners and patients. These strategies must be 3 directions oriented (Ph. Abecassis şi Nathalie Coutinet, 2008, p.128):

- Repositioning products on different markets (switch). Switch "Rx-to-OTC" is a strategy defined as a voluntary transfer of the status of a molecule with compulsory medical prescription (Rx) to the one with an optional prescription (OTC) (S. Hester, 2005, quoted in Ph. Abecassis and Nathalie Coutinet, 2008, pg.128). The switch policies present numerous advantages for companies. They allow the extension of product life cycle. To do this, they must be accompanied by further decisions in terms of price in relation to the market that the product enters. Indeed, contrary to 'princeps' drugs market, the OTC drugs market is not completely set and the product is paid by patients. Prolonging the life of the product due to its change of status is in the extension life of product due to its change is equally a path for companies to compensate a low production rate of new blockbusters.

- Information, training and publicity. Given the competitive pressures and the tendency of shortening of life cycle products drug market, a new drug success depends ever more on capacity of firms to launch it fast in the market. Obviously that the success is guaranteed by achieving market studies and competitive positioning as well as by promotion campaigns (S. Seget, 2007, quoted in Ph. Abecassis and Nathalie Coutinet, 2008, pg.130). Promotion and advertising made by the pharmaceutical industry paying attention to the ones who do prescriptions is old and represents a quite stable proportion of the order of 12% - 15% of turnover. The environmental changes and development of authoritarian or consensual limitations (the development of quality regulations, codes of good practice, etc.) pushing the firms to seek other strategies, less costly and more effective than medical visit (to promote a drug). Besides, all the impact studies show that only exclusive medical visits, in other words unaccompanied by one or more other actions modes for doctors, are found less effective (Grimshaw J.-M. et al., 2004, cited in Ph. Abecassis and Nathalie Coutinet, 2008, pg.130). The pharmaceutical companies tend, thus to reduce the number of health visitors (promoters of their medicines). In parallel, the companies enlarge promotional investments in informing beside exclusive medical visits, respectively in continuous training session, seminars and conferences participation, funding medical magazines, relational marketing with opinion leaders, insurance companies (private insurance, sickness insurance etc) and public institutions. The development perspectives of those medicines within OTC category associated with the patient's decision power increase have determined the companies to enlarge the promoting activities of medicines amongst patients. Thus, the pharmaceutical companies practice two types of marketing actions aiming at patients: a. advertising and promoting campaigns and b. information spreading to retain the consumers with the help of different channels, such as: websites, hot-lines for patients or taking part into patients associations.
- increasing use of brand strategies. These strategies are based either on the medicine reputation within prescribers and patients or the marketing laboratory reputation. Recently, the 'umbrella brands' strategy (or global brands) is rapidly increasing. The umbrella brands are imaginary names common to more medicines and appropriate to a distinctive product. For instance, Avensis company uses Doliprane in order to develop new products such as Dolirhume or Dolitabs.

References:


