VERSITA
DOI:
10.2478/v10286-012-0015-7

Management
2012
Vol.16, No. 1
ISSN 1429-9321

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Pharmaceutical sector in the new reimbursement era

1. Introduction

Both pharmaceutical and biotechnological sector are among the most innovative branches of industry in Europe. Advanced therapeutic methods not only influence the quality of life in the society, but also cover the wider range of aspects including their interrelationships with many other economic areas of the country.

The enterprises with manufacturing plants in Poland have the largest influence on the economy. In turn, the import of foreign pharmaceuticals translates into economic growth measured as operating cash flow.

The objective of this article was to discuss the influence of the changes introduced by the provisions of The Act on Reimbursement of Medicines, Foodstuffs Intended for Particular Nutritional Purposes and Medical Devices from 12th of May, 2011 (Journal of Laws, No. 122, item 696) on the evolution of repayment limits and prices for the patient. Additionally, potential strategy of operations of pharmaceutical enterprises in response to introduced changes was described (Caliskan 2009, Raport Price Waterhouse Coopers (PWC) 2011, 2007).

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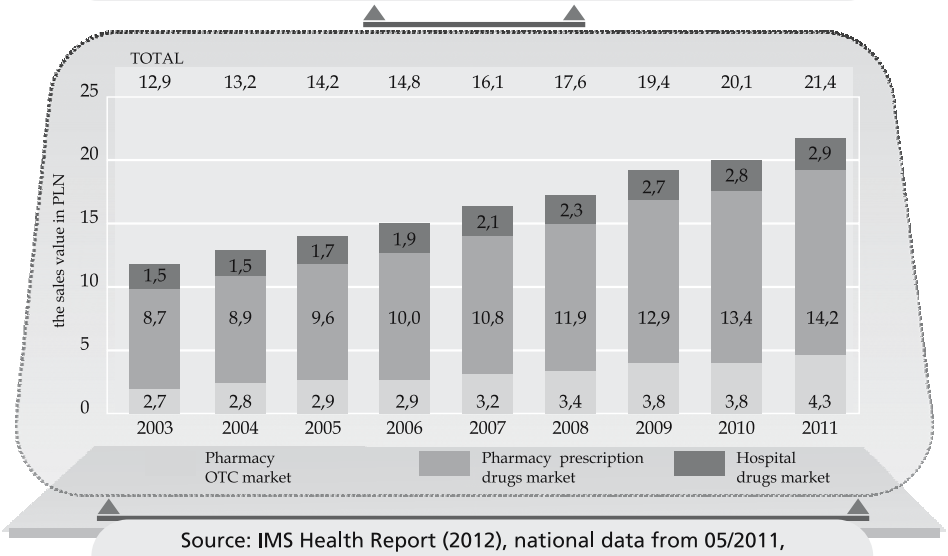
2. The structure of the pharmaceutical market in Poland

The pharmaceutical market in Poland has reached the value of PLN 20.1bn in 2011 (Raport PWC 2011).

In 2010, Rx market accounted for 67% of entire pharmaceutical market; the reimbursed drugs on the pharmacy market accounted for more than a half of the pharmaceutical market's total value. The hospital market has the market share of 13,9%, whereas the corresponding figure of pharmacy OTC market is 19,2%.

Figure 1. The sales value of Polish pharmaceutical market between 2003 and 2011 [PLNbn]



Source: IMS Health Report (2012), national data from 05/2011, net manufacturer's prices (PLN), forecast for 2011, PWC Report (2011)

The market share of generic manufacturers in Polish pharmaceutical market in 2010 accounted for 62% in terms of quantity and 42% in value terms. Innovative drugs cover more than 40% of Rx market in terms of value and 23,5% in quantity terms.

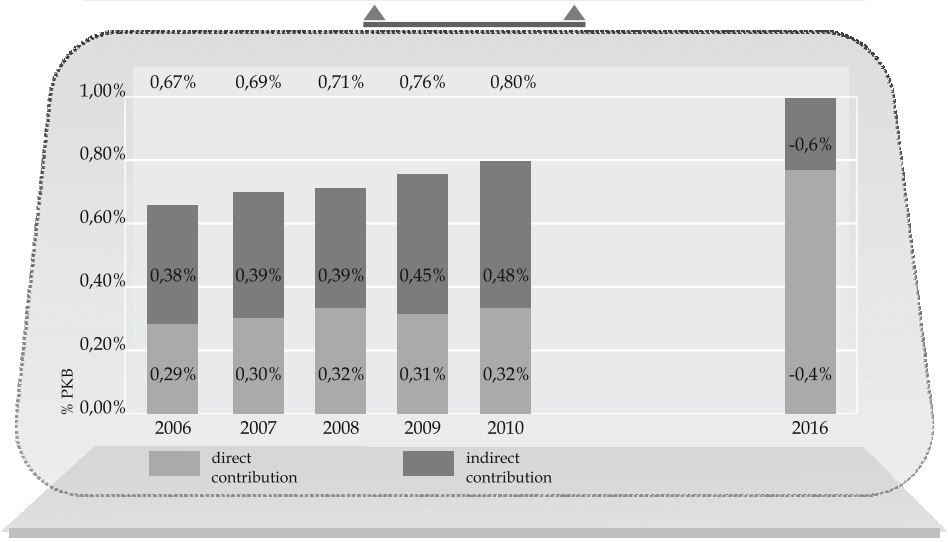
Polish pharmaceutical market mostly consists of generic drugs, with Top 10 players accounting for 50% of its value. The other 50% is divided into approximately 435 companies. All Top 10 companies have their manufacturing plants in Poland. Two of them are Polish companies (PWC Report 2011).

3. The role of pharmaceutical market in economy

According to PWC's report published in 2011, the overall contribution of pharmaceutical sector companies to added value in 2010 has reached 0.80% of Gross Domestic Product (GDP) (direct contribution of 0,32%, indirect contribution of 0,48%). The most (60%) of overall contribution to GDP is generated by innovative pharmaceutical enterprises. It is assumed that the relative contribution of pharmaceutical industry to the generation of added value in Poland will rise for as much as 1% of GDP per year in next few years. The consistent improvement of medical care system, including the creation of the accessibility of the innovations funded by public expenditure would be the basic condition for that increase.

The companies from pharmaceutical sector can presumably generate potential savings for medical care system due to their activities. The most important part of the latter may be: the conduction of prophylactic programs, screening tests,

Figure 2. The impact of pharmaceutical companies on Polish GDP



(the forecast presents the expected levels of GDP and pharmaceutical market increase and does not take into account the influence of The Act on Reimbursement of Medicines, Foodstuffs Intended for Particular Nutritional Purposes and Medical Devices from 12th of May, 2011 on sector soundness; the PWC analysis is based on the Central Office of Statistics data)

Source: PWC Report (2011)

clinical trials, and aiding professional development of healthcare professionals.

The positive impact of pharmaceutical branch on polish economy will probably continue to increase due to the high potential associated with the market size; Poland is the leader of East-Central Europe in the value of drug sales and the sixth largest pharmaceutical market in Europe. Moreover, the implementation of European Union (EU) standards which facilitate business relationships of Poland with other EU markets, as well as the transparency of administrative processes, can be an another beneficial factor (KPMG Report/PMR 2001).

Several factors appear to be potentially threatening in the generally positive impact of pharmaceutical industry on the country's economy. These factors cause some degree of transformation of the entire pharmaceutical sector in Poland, both in strategic and operational aspects. Among them, the most important are: limited access to innovative drugs, administrative handicaps and the provisions of The Reimbursement Act from 12th of May, 2011.

The limited accessibility of innovative drugs to patients is a major problem of Polish healthcare system. Lack of sufficient level of funding from National Fund of Health's (NFZ) reimbursement budget resulting in the unattainability of innovative drug-based therapy is the basic cause of these limitations.

The decision-making process in placing of an innovative drug in reimbursed drug list is long and unpredictable. According to IMS data, patients from Poland only have an access to 48% of those innovative drugs which are accessible in UK or Germany (Raport Price Waterhouse Coopers 2011, KPMG/PMR Report 2011).

The provisions of numerous, important from the pharmaceutical industry's point of view changes-introducing Act on Reimbursement of Medicines, Foodstuffs Intended for Particular Nutritional Purposes and Medical Devices from 12th of May, 2011 which came into force on the 1st of January, 2012, are another factor affecting the pharmaceutical market growth in Poland (especially the Rx section drugs). The aforementioned changes are:

- uncertainty concerning the market position of the product due to the changes in official prices and limits and formal lack of the possibility of price formation in market competition framework,
- standardization of trade terms for distributors,
- decrease of purchasing capacity of pharmacies, lowering of stocks on hand, "passive substitution",
- limitations in pharmacies' and limited service pharmacies' advertising possibilities,
- restricted tools of reimbursed drugs promotion and limitations in the cooperation with persons responsible for the turnover of reimbursed drugs.

The changes concern first and foremost the quality and the principles of the

work with reimbursed products. The character of the changes can be positive, neutral and negative.

Standardized terms and conditions for distributors, the uniformity of an offer and the transparency in the relationships with wholesalers stimulate positive interrelationships in the sector. Increasing role of pharmaceutical enterprises in substantial and educational services range is also a positive aspect of the activity of these entities. The changes with neutral effects on pharmaceutical companies' activity are accompanied with elaborate procedure of reimbursement granting as well as the change of the quality of essential work in pharmacies and medical environment.

The negative changes are mainly associated with the lack of the possibility of market competition involving the use of promotional and trade tools, high risk of decreasing the quantitative turnover and the stocks on hand, limitation of the assortment or even the exclusion of the products from pharmacy offer.

Moreover, as a consequence of many changes, one can observe the lack of direct influence of the company on final product price which is negotiated on ministerial level which makes prediction of the sales and the profits difficult.

4. New reimbursement lists – impact on the patient repayment and National Health Fund (NHF) expenditures

New reimbursement lists, which came into force on 1st of January 2012, predict many changes regarding the taxpayer and the patient. The coming of these lists into force resulted in the wave of protests in the medical environment, largely due to the withdrawal of many drugs important in the therapy from the lists and the shift of the legal responsibility for correct prescription writing on physicians as well as the making the pharmacists responsible for checking those prescriptions. In spite of subsequent correction of the mentioned lists, a part of modern drugs is still not covered by the reimbursement.

Table 1. The impact of new reimbursement lists on the taxpayer and the patients

	Percent change	Valuable change (PLN mln)
Change of reimbursed drug market in retail prices	(-) 3.3%	Change of previous value of reimbursed drug market calculated in retail gross prices (-) PLN 436 mln
Change of patient repayment level	(+) 7.0%	(+) 302 PLN mln

Change of patient copayment level	(+) 3.7 percentage-point (including +5.1pp for generic drugs and 1.6pp for innovative drugs)	In 2011 the patient paid on average 34.1% extra to the price of the reimbursed drug; after the change in 2012 he will pay 37.8% extra.
Change of NHF reimbursement level	(-) 8.9%	(-) 738 PLN mln
Change of the average price for the patient	(+) 3.1%	In 2011 the patient paid on average PLN 9.5 extra to the price of the reimbursed drug; after the change in 2012 he will pay PLN 9.8 extra.
Change of the average price for the patient (including the drugs removed from the new lists)	(+) 7.3%	In 2011 the patient paid on average PLN 9.32 extra to the price of the reimbursed drug; after the change in 2012 he will pay PLN 10 extra.

(the data based on the Announcements of Ministry of Health No. 78 from 23rd of December 2011 and No. 79 from 29th of December 2011 concerning the list of reimbursed medicines, foodstuffs intended for particular nutritional purposes and medical devices for 1st of January 2012)

Source: IMS Health Report (2012)

Until the end of 2011, the level of NHF expenditures and patient expenditures were dependent upon 3 aspects, i.e., drug retail prices, repayment level and the limit level determined by the price of the cheapest drug in a given group.

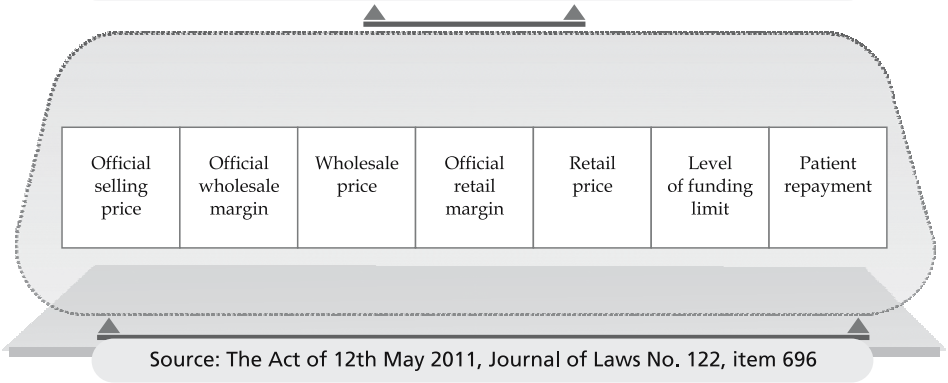
New reimbursement lists, effective from the 1st of January 2012, introduce newly negotiated, official sales prices, limit groups and limit values for reimbursed drugs. The level of NHF expenditures and patient expenditures are additionally ruled by fixed prices and fixed margins, the tax structure of the limit group, and the consumption structure in a given group which affects the level of the funding limit. In summary, the current price actually influences the NHF costs and patient repayment to a lesser degree.

Table 2. Trends in reimbursed product prices

Rules valid until 31.12.2011	New rules, valid from 01.01.2012
Maximum selling price	Official selling price
Maximum wholesale and retail margins	Fixed wholesale and retail margins
	Retail margin calculated on the basis of wholesale price of the limit-determining product

Source: The Act of 12th May 2011, Journal of Laws No. 122, item 696

Figure 3. The price tract of reimbursed products – the rules effective from 01.01.2012



Source: The Act of 12th May 2011, Journal of Laws No. 122, item 696

Official selling price:

- product selling price determined as a result of administrative decision concerning the reimbursement allowance of a given product by Ministry of Health,
- gross price,
- used by the manufacturer when the product is sold to the wholesale.
- Official wholesale margin:
- in 2012, it is fixed at the level of 7% of the official retail price (the fixed level is 6% in 2013 and 5% from 2014),
- it can be shared by wholesalers (when the product is sold from one wholesale to another).

Wholesale price = official retail price + official wholesale margin:
the wholesale must use this price when the product is sold to the pharmacy.
Official retail margin:

- is calculated based on the wholesale price of the product, which, at the same time, is the basis of the limit,
- its level is calculated according to the table 3.

Retail price = official selling price + official wholesale margin. The pharmacy is obliged to use this price when the product is sold to the patient (The Act from 12th of May 2011, Journal of Laws No. 112, item 696).

Table 3. Official retail margin calculated based on the drug, the intended foodstuff or the medical product wholesale price which is the basis for the limit value in a given limit group, amounted to:

from [PLN]	to [PLN]	Margin rule
-	5.00	40%
5.01	10.00	PLN 2.00 + 30% *(x-5.00)
10.01	20.00	PLN 3.50 + 20%*(x-10.00)
20.01	40.00	PLN 5.50 + 15%*(x-20.00)
40.01	80.00	PLN 8.50 + 10%*(40.00)
80.01	160.00	PLN 12.50 + 5%*(x-80.00)
160.01	320.00	PLN 16.50 + 2.5%*(x-160.00)
320.01	640.00	PLN 20.50 + 2.5%*(x-320.00)
640.01	1 280.00	PLN 28.50 + 2.5%*(x-640.00)
1280.01		PLN 44.50 + 1.25%*(x-1280.00)

Source: The Act of 12th of May 2011, Journal of Laws No. 122, item 696

Official selling prices, as well as official wholesale and retail margins, are fixed.

Table 4. Types and levels of repayment for reimbursed drugs

Free of charge	A drug, medicinal product with proven efficacy towards malignant cancer, psychotic disorder, mental disability or developmental disorder or infectious disease particularly hazardous to population; or drug, foodstuff intended for particular medical purposes used as a part of a drug-based program
Lump sum	A drug, foodstuff intended for particular medical purposes or medicinal product requiring its use over a period longer than 30 days or whose monthly cost of use for the beneficiary would exceed 5% minimum monthly salary if the repayment amounted to 30% of funding limit; also, a drug, foodstuff intended for particular medical purposes or medicinal product requiring its use over a period not longer than 30 days or whose monthly cost of use for the beneficiary would exceed 30% minimum monthly salary if the repayment amounted to 50% of funding limit
Repayment amounting to 50% of funding limit	a drug, foodstuff intended for particular medical purposes or medicinal product requiring its use over a period not longer than 30 days

Repayment amounting to 30% of funding limit	a drug, foodstuff intended for particular medical purposes or medicinal product which was not qualified to the above-mentioned repayment levels

Source: The Act of 12th of May 2011, Journal of Laws No. 122, item 696

Table 5. Changes in the repayment level of reimbursed products

	List of reimbursed drugs, valid to 31.12.2011	List of reimbursed drugs, valid from 01.01.2012	
Repayment level	Number of drugs	Number of drugs	Percent change
Free of charge	344	231	-33%
Lump sum	1380	1232	-11%
Repayment amounting to 50% of funding limit	931	425	-54%
Repayment amounting to 30% of funding limit	674	847	26%

Sources: The Act of 12th of May 2011, Journal of Laws No. 122, item 696; The Announcement of Ministry of Health No. 78 from 23rd of December 2011 and No. 79 from 29th of December 2011; IMS Health Report, 2012

Price changes, fixed prices and margins, as well as limit changes increase the overall patient repayment level in 45 illnesses by PLN 572bn. This increase in patient repayment level was observed for both generic and innovative drugs. Patient copayment amount can probably be reduced only in the case of lowering official selling price or the increase of funding level by NHF. NHF will probably reach large savings as a result of the price and repayment level changes (IMS Health Report, 2012).

Table 6. Estimated list of NHF savings level and the increase of patient repayment for the drugs and medicinal products resulting from the introduction of new reimbursement lists in 2012

Disease entity	NHF savings level	Increase in the level of patient repayment by
Diabetes (test strips for monitoring of glycemia)	PLN 169.7 mln	PLN 122.4 mln
Schizophrenia	PLN 122.4 mln	PLN 15.9 mln
Asthma	PLN 74.3 mln	PLN 48 mln

Peptic ulceration	PLN 71.1 mln	PLN 73.3 mln
Alzheimer disease	PLN 62.4 mln	PLN 43.9 mln
Malignant diseases	PLN 38.2 mln	PLN 6.6 mln
Epilepsy	PLN 35.5 mln	PLN 32.1 mln

Source: The Act of 12th of May 2012, Journal of Laws No. 122, item 696. The Announcement of Ministry of Health No. 78 from 23rd of December 2011 and No. 79 from 29th of December 2011, IMS Health Report 2012

The disease entities presented in the table account for the expenditures on the level of PLN 3,2bn coming from NHF's reimbursement budget plus PLN 583mln of patient expenditures, keeping in mind that the latter will increase to the level of PLN 925mln (IMS Health Report 2012).

5. The operational strategy of the pharmaceutical sector in new era of reimbursement

The Reimbursement Act introduces revolutionary changes in many fields of operation of pharmaceutical companies. The change of the approach to the personnel of medical institutions and pharmacies also caused the behavior of doctors, nurses and pharmacists to change. All types of activities that could lead to the increase in sales numbers of the National Fund of Health-co-funded drug and medicinal products unjustified by medical needs are now restricted. Article 49, Paragraph 3 of The Reimbursement Act covers the list of prohibited activities associated with the reimbursed products. That list includes the prohibition of: conditioned sales, outlets, discounts, compensations, package deals, loyalty programs, donations, awards, gifts, souvenirs, sponsored services, all types of coupons, vouchers, and other non-listed profits.

The introduced restrictions do not concern the entitled persons (i.e., doctors and pharmacists) only, but also all entrepreneurs, their employees directly and indirectly engaged in the pharmaceutical sector, and patients (The Act from 12th of May 2011, Journal of Laws No. 122, item 696).

How to administer the brand of reimbursed product in accordance with the new Act? The professional knowledge-based promotion is still not prohibited in any way. The legislator does not limit educational activities aimed at delivering reliable information concerning the drug's mechanism of action or efficacy. Doctors and pharmacists can accept an invitation for training or conference organized by pharmaceutical company or with its involvement provided that the extent of the training includes professional knowledge and not the promotion of a given product and the training itself is not a platform for transferring the

benefits other than substantial ones. Also, the Act does not limit to any degree the carrying out the epidemiological studies or the studies on the reimbursed products' activity, provided that it is not a form of prescription contracting of the specific product and the physician/scientist is rewarded according to market standards. The support from the pharmaceutical companies sales teams in the development of educational programs in pharmacies concerning the pharmaceutical care will certainly be an important element of their work. The mentioned care can have the large effect on the increase of patient educational level, particularly within the frames of the prophylaxis of many diseases.

The Reimbursement Act does not modify in any way the strategic activities of companies which are based on the sales of products belonging to over-the-counter (OTC) category, dietary supplements or non-reimbursed medicinal products. Exactly in 20011-2013, the supplement market in Poland is expected to develop intensively, with the rate of 9%-15% per year. The development dynamics of the sector will probably be slower than in the period of 2006-2008; however, it is noteworthy that it is still very high and higher than, for example, that for OTC drug and medicinal product sectors. The trends present in last few years, like population aging, the increase of interest in self-medication, healthy lifestyle and appearance as well as interest in products of natural and herbal origin, are assumed to continue (PMR Report 2011).

Summary

Pharmaceutical sector in the new reimbursement era

The topics taken into consideration in this article concern the role of pharmaceutical sector in country's economy and the influence of factors limiting economic growth of the branch, mainly provisions of The Act on Reimbursement of Medicines, Foodstuffs Intended for Particular Nutritional Purposes and Medical Devices from 12th of May, 2011. New rules introduced by this Act, affecting the price evolution of the reimbursed products (i.e., official selling price, fixed wholesale and retail margins, retail margin calculated on the basis of wholesale price of the limit-determining product), had an impact on the increase of patient repayment level for the drugs, the decrease of NHF reimbursement and spending level, and the drop of the value of reimbursed drug market. Such a situation caused the increase of patient repayment level for the reimbursed drugs in many disease entities.

In spite of many restrictions imposed by the mentioned Act, the perspectives of pharmaceutical market's growth in Poland are

positive. In last few months, pharmaceutical sector has been prepared for the entry of new Reimbursement Act. More than 60% of requested pharmaceutical companies estimated positively current market situation in Poland. Among the surveyed ones, increasing sales numbers and improving financial results are indicated as the causes of such estimation (KPMG/PMR Report 2011).
Every single pharmaceutical enterprise is the company undergoing the same rules as companies operating in other fields, which means the necessity of profit taking. During the analysis of the pharmaceutical market one can see some complexity and specificity, particularly due to the offered products and the sources of their funding, the level of regulation and the conservatism of the market itself which is one of the highest in the entire business. In spite of numerous limitations, most of enterprises realize the strategy of a continuous growth due to successful selling and marketing activities.

Streszczenie

Sektor farmaceutyczny w nowej erze refundacyjnej
Rozważania podjęte w artykule dotyczą roli sektora farmaceutycznego w gospodarce krajowej oraz wpływu czynników ograniczających ten rozwój - głównie zapisów Ustawy z dnia 12 maja 2011 roku o refundacji leków, środków spożywczych specjalnego przeznaczenia żywieniowego i wyrobów medycznych. Wprowadzone nowe zasady wpływające na kształtowanie się cen produktów podlegających refundacji (urzędowa cena zbytu, sztywne marże hurtowa i detaliczne, marża detaliczna liczona od ceny hurtowej produktu wyznaczającego limit) wpłynęły na wzrost poziomu odpłatności pacjenta za produkty refundowane, zmniejszenie poziomu refundacji i wydatków NFZ oraz spadek wartości rynków produktów refundowanych. Liczba produktów objętych 30% poziomem odpłatności wzrosła w stosunku do wszystkich pozostałych produktów objętych statusem refundacyjnym. Taka sytuacja przyczyniła się do wzrostu poziomu odpłatności pacjentów za produkty refundowane w wielu jednostkach chorobowych.
Pomimo wielu ograniczeń narzucanych przez wspomnianą ustawę perspektywy rozwoju rynku farmaceutycznego w Polsce są pozytywne. Sektor farmaceutyczny w ciągu ostatnich kilku miesięcy przygotowywał się do wejścia w życie nowej ustawy refundacyjnej. Ponad 60% badanych firm farmaceutycznych w Polsce dobrze lub

bardzo dobrze ocenia obecną sytuacje na rynku. Jako przyczynę takiego stanu ankietowani wskazują wzrost sprzedaży oraz poprawiające się wyniki finansowe (Raport KPMG/PMR 2011).
Każde przedsiębiorstwo farmaceutyczne to firma, która rządzi się takimi samymi prawami jak przedsiębiorstwa innych branż, co oznacza konieczność realizowania zysku. Analizując rynek branży farmaceutycznej można zauważyć pewną złożoność i specyficzność – szczególnie z uwagi na produkty jakie oferuje oraz ich źródła finansowania, poziom regulacji i konserwatyzm samego rynku, który jest jednym z najwyższych w całym biznesie. Pomimo wielu ograniczeń większość przedsiębiorstw realizuje strategię ciągłego wzrostu dzięki skutecznym działaniom sprzedażowo – marketingowym.

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