The Polish Pharmaceutical Market

Its Condition and Prospects for Growth until 2011, as Seen by the Largest Pharmaceutical Companies
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Introduction

The pharmaceutical market in Poland has developed dynamically in the past five years, weathering difficult market conditions. As demonstrated by the results of our study, the current economic situation linked to the global economic crisis has not affected the positive performance of the pharmaceutical sector, nor has it had an adverse effect on the optimistic mood which prevails among pharmaceutical companies in Poland.

This report, which we are pleased to present, is a result of a survey conducted jointly by KPMG and PMR among the largest pharmaceutical companies operating on the Polish market. The purposes of the study were as follows: to diagnose the current situation of the pharmaceutical market; to identify actions undertaken by the surveyed companies in the face of the economic downturn, and to assess the sector’s growth prospects for the coming years, whilst taking into consideration amendments to current regulations pertaining to the pharmaceutical market as well as transformations of pharmaceutical distribution models.

As demonstrated by the results of our survey, the current situation of the pharmaceutical industry is good, despite the noticeable impact of the economic downturn. Pharmaceutical companies are generally upbeat about future prospects of the industry, and predict continued growth for the pharmaceutical sector. One thing that reflects this fact is that over one half of the companies surveyed plan to increase investments in employee development and production infrastructure in the next 12 months.

We hope that the results of our survey, as presented in this report, will be a valuable source of information about the current standing of the pharmaceutical sector in Poland.

We would like to extend our sincere thanks to all the companies who agreed to take part in the survey and to share their knowledge and opinions with us.

Marcin Rudnicki  
Partner  
Head of the Pharmaceuticals Industry  
KPMG

Karol Kołt  
Managing Director  
PMR
Key findings

The pharmaceutical market on the path of rapid growth

In 2008 the pharmaceutical market in Poland was worth PLN 24.1bn, which represented 11.5% growth in comparison with 2007. At present, it is among the areas of the Polish economy boasting the strongest future growth prospects. According to our forecasts, in 2009-2011 the CAGR (Compound Annual Growth Rate) will be 7.4%, whereas pharmaceutical companies expect it to reach approx. 6%. In terms of sales value, the Polish pharmaceutical market is the sixth largest in the European Union, while in terms of the rate of sales growth (as expressed in euro), it was the second fastest growing market in the EU in 2007-2008.

Pharmaceutical companies weather the economic downturn

The economic downturn has had little effect on the mood within the pharmaceutical industry. More than 60% of the surveyed companies described the current market situation as “good” or ‘very good’. Polish companies are slightly more optimistic in their assessments than enterprises with a majority share of foreign capital. Over one half of the companies surveyed cited increased sales and improving financial performance as factors contributing to the positive mood prevailing in the pharmaceutical sector. A mere one third of the respondents claimed that the situation of their companies had deteriorated, when compared to the previous year’s performance.

New drugs drive growth on the pharmaceutical market

Almost one third of the surveyed companies pointed to new pharmaceuticals as the factor with the strongest bearing on the growth of their company, and on the sector as a whole. Other major reasons fostering growth included an overall increase in the affluence of the Polish society and better access to reimbursement. Nearly one half of respondents named antineoplastic drugs as a pharmaceuticals category which would appear on the Polish market in the coming two years. Forty percent of the surveyed companies planned to introduce three to ten new drugs by the end of 2009. Less than one third of the respondents planned no new launches on the market.

Online pharmacies are the fastest growing distribution channel

Online pharmacies will be the fastest growing sales channel in the coming 12 months. A notable 80% of the companies surveyed predict that distribution through online pharmacies will develop
faster than the pharmacy sales market as a whole. Importantly, over one half of the respondents predict that drug sales through other online stores will also grow at a higher rate than the market as a whole. This means that companies expect continued growth in illegal trade in pharmaceuticals in Poland (online sales of drugs by companies other than online pharmacies are banned in Poland). Distribution on an exclusivity basis and through herbal and medicinal stores are the only two channels where growth is expected to be below the market average.

No threat to investments in the pharmaceutical industry

The economic downturn has had no negative impact on capital expenditure programs in the pharmaceutical industry. On the contrary, more than 60% of the surveyed companies plan to step up expenditure on employee development in the coming 12 months. A similar percentage of surveyed companies also speak of increasing expenses on production assets. As far as research and development expenditure is concerned, companies planning to maintain the current level of R&D spending are slightly greater in number, but still the percentage of those which intend to increase R&D expenses is high, at over 40%.

Restrictions on advertising and promotion of pharmaceuticals, and the lack of transparency of the government’s drug policy are the strongest barriers to business

In addition to the frequently quoted factors accompanying the financial crisis (such as difficulties in accessing loans and the high volatility and unpredictability of foreign exchange rates), pharmaceutical companies are particularly constrained by restrictions on advertising and promotion of drugs set forth in the ordinance on the advertising of pharmaceutical, dated November 2008. They are further constrained by the lack of transparency in policies with regard drug reimbursement, which results, for instance, in the unequal treatment of manufacturers of innovative and generic products.

Introduction of fixed margins will have an adverse effect on drug manufacturers

The two most controversial provisions which the Ministry of Health plans to include in the amended Pharmaceutical Law (concerning the introduction of fixed margins on reimbursed drugs and stricter regulation of anti-concentration rules) will have a varying impact on the pharmaceutical market. In the former case, the maximum fixed margin on subsidized drugs (both wholesale and retail margins) may not be freely reduced by wholesalers or pharmacies, as it has been done up until now, and the subsidized pharmaceuticals will be sold at the same price in all pharmacies. In the opinion of the surveyed companies, this amendment will have an adverse effect on drug distributors, though it will be beneficial to patients. In the case of anti-concentration rules, the negative impact will be felt mostly by distributors and pharmacies, while the situation of drug manufacturers will remain unchanged.
About the Study

Objectives of the study

The main objective of the study was to assess the current situation of the pharmaceutical market and to explore the market players’ predictions concerning the growth of the sector in the next two years. Our intention was also to compile information on activities undertaken by pharmaceutical companies in the face of the crisis gripping the world’s economy, and the anticipated impact of the planned amendments to legislation on the development of the pharmaceutical market.

Research methodology

The study was carried out in July 2009 by PMR, a research company, at the request of KPMG. PMR interviewed representatives of large companies manufacturing pharmaceuticals and dietary supplements from the Polish market. The Computer Assisted Telephone Interviewing method (CATI) was applied. In total, 75 interviews were conducted with companies from the sector.

Respondents

The respondents in the study were mostly managers and individuals with extensive knowledge about the condition of their respective companies and about the Polish pharmaceutical market. More specifically, interviews were held with executives and managers in charge of sales and marketing (36%), presidents and managing directors (12%), development managers (10%) and people in managerial positions (17%).

Positions held by respondents at their companies

N=75
Source: KPMG, PMR Research, 2009
Approximately a quarter of all respondents held other posts (specialists, analysts, etc.) but were adequately qualified to provide valuable information during the interview.

**Employment**

- >250 employees: 20%
- 51-250 employees: 56%
- <50 employees: 24%

N= 74. data and ‘don’t know’ excluded.
Source: KPMG, PMR Research, 2009

Over one half of the surveyed enterprises were middle-sized companies employing between 51 and 250 people. Companies employing up to 50 employees accounted for nearly a quarter of the respondents whereas enterprises with more than 250 employees represented about one fifth of all companies surveyed.

**Core business segment of surveyed pharmaceutical companies**

- Innovative pharmaceuticals: 35%
- Generic pharmaceuticals: 43%
- Dietary supplements: 22%
- Innovative pharmaceuticals: 35%

N= 72. data and ‘don’t know’ excluded.
Source: KPMG, PMR Research, 2009
The largest proportion of the companies surveyed (43%) were those whose core activity involves the production of generic medicines. More than one third of the companies surveyed chiefly produce innovative drugs. The smallest proportion (22%) were those whose predominant activity concerns dietary supplements.

Almost a half of the companies interviewed (47%) are enterprises with major foreign equity participation. The remaining companies are Polish (which means that they have no foreign investor with a major influence on their activities).

**Revenue of surveyed pharmaceutical companies in 2008**

<table>
<thead>
<tr>
<th>Revenue Range</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>PLN 20m-50m</td>
<td>29%</td>
</tr>
<tr>
<td>PLN 50m-100m</td>
<td>13%</td>
</tr>
<tr>
<td>PLN 100m-500m</td>
<td>34%</td>
</tr>
<tr>
<td>&gt;PLN 500m</td>
<td>3%</td>
</tr>
<tr>
<td>&lt;PLN 20m</td>
<td>2%</td>
</tr>
</tbody>
</table>

N = 68. Missing data, refusals and 'don’t know' excluded.
Missing data was completed from available sources on companies’ revenues.
Source: KPMG, PMR Research, 2009

Most of the companies interviewed in the survey generate revenue in the middle range. Among the companies which answered the question about 2008 revenues, 34% reported an income between PLN 100 million and 500 million and the same proportion had a turnover of PLN 20 million - 100 million. Companies generating under PLN 20 million represent 29% of the total sample. Additionally, two interviews were held with companies generating in excess of PLN 500 million.
Assessment of the situation on the pharmaceutical market

Pharmaceutical companies operating in Poland provided positive assessments concerning the current situation in their sector. Nobody gave an extremely negative response, and a mere 7% of interviewees assessed the current situation as 'rather bad.' Over 60% of the respondents expressed a view that the situation was either 'very good' or 'good.'

Assessment of current situation of Polish pharmaceutical market by companies operating on this market

N=75.
Source: KPMG, PMR Research, 2009

Polish companies provided more favorable assessments of the market situation as compared to companies with substantial foreign interests. Responses provided by those companies included significantly more positive assessments. For instance, 'good' was the response chosen by two thirds of majority owned Polish companies, and under 50% of companies with foreign capital.

Assessment of current situation of Polish pharmaceutical market depending on company ownership

N=72. Missing data and ‘don’t know’ excluded.
Source: KPMG, PMR Research, 2009

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Assessment of the current market situation varied, depending on the respondents’ core business segment. Enterprises operating mostly in the dietary supplement segment were significantly more optimistic about the current market situation. Manufacturers of generic drugs were in the middle of the range. In our opinion, this distribution of opinions mostly depends on the mood within individual market segments. Growth in the value of sales of the dietary supplements industry has exceeded 20% per annum over the past few years. Likewise, the government’s drug subsidizing policy has supported manufacturers of generic medications for many years, while innovative drugs are rarely added to the list of reimbursed drugs.

### Assessment of current situation of Polish pharmaceutical market depending on core business segment

<table>
<thead>
<tr>
<th></th>
<th>Innovative pharmaceuticals</th>
<th>Generic pharmaceuticals</th>
<th>Dietary supplements</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rather bad</td>
<td>12%</td>
<td>6%</td>
<td>25%</td>
</tr>
<tr>
<td>Neither good nor bad</td>
<td>36%</td>
<td>29%</td>
<td>62%</td>
</tr>
<tr>
<td>Rather good</td>
<td>52%</td>
<td>62%</td>
<td>13%</td>
</tr>
<tr>
<td>Very good</td>
<td>3%</td>
<td>3%</td>
<td></td>
</tr>
</tbody>
</table>

N=72. Missing data and ‘don’t know’ excluded.
Source: KPMG, PMR Research, 2009

The respondents were also asked to provide grounds for their opinions on the current market situation. The reasons for positive assessments mostly concerned high sales figures of the respondents’ companies, and the generally good standing of the pharmaceutical sector during the course of the year. In both cases, over a half of the respondents who assessed the current market situation as ‘good’ or ‘very good’ cited those reasons.

### Reasons for positive assessments of current pharmaceutical market situation in Poland

<table>
<thead>
<tr>
<th>Reason</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sales growth, improved financial results</td>
<td>54%</td>
</tr>
<tr>
<td>Good condition / stability of pharmaceutical market</td>
<td>52%</td>
</tr>
<tr>
<td>Good situation in labour market of the pharmaceutical sector</td>
<td>7%</td>
</tr>
<tr>
<td>Increased customer interest / continued demand for pharmaceuticals</td>
<td>4%</td>
</tr>
<tr>
<td>Other</td>
<td>11%</td>
</tr>
</tbody>
</table>

N=46. Based on answers of respondents who provided positive assessments of the market situation. Multiple responses were allowed.
Source: KPMG, PMR Research, 2009
It appears that in the first half of the year, the pharmaceutical industry still managed to escape the adverse impact of the global crisis, which severely affected other sectors of the Polish and the global economy as a whole. This situation reflects the fact that no less than one half of the market represented by sales of reimbursed pharmaceuticals is not subject to the rules of the market as much as are other sectors, and it is basically shaped by changes to the government’s drug reimbursement policy. The crisis also helped boost sales of over-the-counter (OTC) drugs since Poles were more willing to choose non-prescription drugs as they feared job loss, preferring this option to seeing a doctor. Additionally, another contributing factor to the market’s growth was a large number of infections during the epidemic season. As a result, in the first six months of the year, the value of the Polish pharmaceutical market expanded by 8.6% year on year, with the OTC market having increased by 12% in terms of value.*

The respondents who thought that the market situation was neither good nor bad generally based their opinions on the financial performance of their companies, which has stayed at level comparable to the year before (one third of respondents who were surveyed assessed the market situation as neutral).

Those who described the market situation as ‘rather good’ mentioned the following reasons:

- negative assessment of the directions of the government’s drug reimbursement policy and lack of transparency in the drug reimbursement process
- overly complicated drug registration procedure
- strong competition on the market
- adverse impact of foreign exchange rates differences.

**Assessment of changes in pharmaceutical market situation relative to 2008**

In the first half of 2009, the pharmaceutical industry continued to be unaffected by the negative consequences of the crisis

The answers on how the pharmaceutical market situation changed as compared to 2008 were reasonably balanced. Only some respondents mentioned a significant change to the market situation – for better or for worse. Forty-one percent of respondents claimed that the market situation did not change at all. According to 23% of the interviewees, it slightly improved, whereas approximately one third said that the market situation slightly deteriorated since 2008.

* PharmaExpert data relating to pharmacy sales at retail prices.
Assessments of the direction of market situation changes were to a large extent based on the financial results of respondents – this justification was the most frequently cited answer, regardless of whether the market changes were viewed positively, neutrally or negatively.

The respondents who believed that the market situation had improved since the previous year described overall market growth as the reason for the good situation. Only a few respondents drew attention to the ongoing sorting out of the legislative environment (e.g. concerning drug reimbursement rules).

Reasons cited by respondents who thought that the market situation had deteriorated included various consequences of the crisis, e.g. exchange rates differences and late payments from business partners. Once in a while, the respondents also mentioned the following reasons for their opinions:

- negative impact of the ordinance on drug advertising (impeded access to doctors)
- the government’s drug reimbursement policy (perceived as wrong by the respondents) and changes to the lists of reimbursed drugs
- strong market competition
- poor financial liquidity of wholesalers
- adverse impact of consolidation of the wholesale market which forces a cooperation model based on financial performance rather than partnership.

Opinions on changes to the pharmaceutical market in the past year slightly varied, depending on the core business segment of the interviewed companies.

The changes on the pharmaceutical market during the last year have primarily affected the segment of dietary supplements

Assessment of changes in pharmaceutical market relative to 2008 depending on core business segment

N=70. Missing data and ‘don’t know’ excluded.
Source: KPMG, PMR Research, 2009

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Although companies chiefly operating in the dietary supplement segment assessed the current situation of the pharmaceutical market to be better when compared to assessments provided by representatives of other segments, they were the group to experience a change for the worse in 2009 – more so than any other segment. However, the dietary supplement sector also included companies which reported a marked improvement in their situation.

In our opinion, this situation is related to the nature of the products offered. In previous years, sales of dietary supplements recorded a substantial double-figure annual growth. Currently, sales growth can be somewhat lower since, during the economic downturn, consumers are more likely to give up supplementary products, such as dietary supplements, than pharmaceuticals. The mood of the industry may further deteriorate due to the near end of 2009. Borderline products (i.e. those which may be seen as either pharmaceuticals or dietary supplements), which have been recognized as dietary supplements until now, may remain in trade until 31 December 2009. However, after said date, these products will have to be registered as medicines, which will entail a significantly more complex procedure than the one applied in the case of dietary supplements.

Anticipated developments on the pharmaceutical market in the coming years

Predictions of pharmaceutical companies about changes in pharmaceutical market in 2010 relative to 2009

- Will remain unchanged 33%
- Will rather improve 45%
- Will rather deteriorate 22%

N=69. Missing data and ‘don’t know’ excluded.
Source: KPMG, PMR Research, 2009

The situation of the Polish pharmaceutical market will improve in 2010
The respondents showed considerable optimism in their predictions about the development of the situation on the Polish pharmaceutical market. Forty-five percent of them stated that the situation would improve whereas half as many expressed a contrary opinion. More or less one third of the respondents did not anticipate any major changes to the pharmaceutical market in 2010.

Predictions about direction of changes in value of Polish pharmaceutical market in a given year relative to the previous year

<table>
<thead>
<tr>
<th>Year</th>
<th>Will increase</th>
<th>Will remain unchanged</th>
<th>Will decrease</th>
</tr>
</thead>
<tbody>
<tr>
<td>2009</td>
<td>81%</td>
<td>14%</td>
<td>5%</td>
</tr>
<tr>
<td>2010</td>
<td>77%</td>
<td>20%</td>
<td>3%</td>
</tr>
<tr>
<td>2011</td>
<td>80%</td>
<td>20%</td>
<td>0%</td>
</tr>
</tbody>
</table>

Respondents expect an average growth of approximately 6% in the coming two years

N=72 for estimates concerning 2009.
N=69 for estimates concerning 2010.
N=64 for estimates concerning 2011.
Missing data and ‘don’t know’ excluded.
Source: KPMG, PMR Research, 2009

Although one third of the respondents observed a slump on the pharmaceutical market in 2009 as compared to 2008 and over one fifth expected the deterioration to continue, a mere 5% of respondents believed that the 2009 market value would be lower than in 2008, and an even smaller proportion predicted that the market value would shrink after 2009. Less than 80% of the respondents expected that the value of the pharmaceutical market would increase in the next two years. According to the respondents, the average expected growth will be around 6% year-on-year in the coming two years.
Determinants of growth and barriers to development of the pharmaceutical market in Poland

Although the current market situation in Poland appears to be unaffected by the adverse impact of the global financial crisis (judging by the reported market growth rates), our respondents claimed that the crisis was the main barrier to doing business – as illustrated by positive responses from one third of the respondents. Most frequently, they mentioned difficulty in obtaining bank loans, adverse developments in the zloty exchange rate and Poles’ declining purchasing power.

Most frequent barriers to doing business in Polish pharmaceutical market

- Ongoing economic downturn in Poland and worldwide: 36%
- Ordinance on pharmaceutical advertising of November 2008: 31%
- Lack of transparency in the state’s pharmaceutical policy: 25%
- Unclear and confusing law, bureaucracy: 20%
- Too strong competition in pharmaceutical market: 15%
- Long and complicated drug registration procedure in Poland: 13%
- Other legal changes: 8%
- Unfavourable effects of drug law harmonisation: 7%
- Inefficient operation of the Office for Registration of Medicinal Products (URPL) and the Main Pharmaceutical Inspectorate (GIF): 7%

N=75. Respondents were allowed to provide up to three responses. Source: KPMG, PMR Research, 2009

One in four companies criticizes the government’s reimbursement policy.
Another barrier, mentioned by one third of the respondents, concerned deterioration of the conditions for advertising and promoting medicines. This development was brought about by the ordinance on drug advertising that came into force in November and December 2008. As a result of this new regulation, contacts between medical representatives and physicians were made much more difficult. Furthermore, restrictions were also imposed on audio-visual advertising.

A quarter of the respondents were critical of the government’s drug reimbursement policy. In the opinion of companies present on the market, the policy is hardly transparent, which is the key objection stated against it. Manufacturers of innovative drugs and producers of generics are not treated equally in decisions concerning drug reimbursement; further, the provisions of the drug reimbursement law are not being complied with (time limits for adopting drug reimbursement decisions are not being met). Additionally, the lists of reimbursed drugs are updated too rarely. Those surveyed believe that funds spent on drug reimbursement are not being allocated properly and the well-being of patients is not taken into account in the process.

One in five respondents also mentioned the legislative confusion, obscurity of the law and its failure to adapt to EU legislative requirements. Furthermore, 8% of the respondents pointed out recent legal changes as introducing additional barriers to doing business in the pharmaceutical industry (e.g. packaging of pharmaceuticals must have Braille embossing, and regulations pertaining to dietary supplements are more restrictive).

One seventh of the respondents mentioned excessive competition within the Polish market at present. Thirteen percent of responses focused on the lengthy and complicated drug registration procedure. A mere 7% of respondents indicated the adverse impact of harmonization on the market.

Other factors mentioned by respondents which were not listed in the graph included:

- consolidation of wholesalers
- pricing regulations unfavorable to respondents
- poor accessibility of capital expenditure funding
- deterioration/instability of the political situation
- poor financial liquidity of business partners
- various restrictions on advertising.

In terms of factors facilitating operations in the pharmaceutical sector in Poland, respondents’ answers were more varied than their responses on market barriers.
Factors which could have the strongest influence on operations in Polish pharmaceutical market

- **Introduction of new products to the market**: 30%
- **Overall increase in wealth of population**: 14%
- **Access to reimbursement**: 12%
- **Access to funds for capital expenditure**: 8%
- **Sorting out the legal order**: 7%
- **Marketing efforts**: 7%
- **Improving quality of products**: 5%
- **Expansion into markets outside of Poland**: 5%
- **Increased awareness of Poles regarding health issues**: 5%
- **Increased number of sales representatives**: 5%

N=73. “Don’t know” responses excluded. Respondents could give up to three responses.
Source: KPMG, PMR Research, 2009

For nearly one third of the respondents, factors such as new product launches and new portfolio extensions would drive their growth on the Polish market.

For almost one third of the respondents, new product launches or diversification of their product portfolios by adding new ranges of products (e.g. dietary supplements) would foster growth of their operations on the Polish market. Fourteen percent of companies claim that they would benefit from an overall improvement of Poles’ financial situation.

One in eight companies stated that a market success would mean that their medicines would be included in the reimbursement lists. A further 8% mentioned access to funds for capital expenditure. Respondents also referred to an increased number of sales representatives, improved quality of products, expansion into foreign markets and increased health awareness among Poles – each one of these issues garnered a mere 5% of the responses.

Other factors mentioned by a few respondents which were not listed in the figure above were as follows:
- consolidation or a merger with another company
- new manufacturing methods
- innovations
- greater independence of the Office for Registration of Medicinal Products of the Ministry of Health
- demographic trends (e.g. ageing population)
- direct distribution or other logistics measures reducing the delivery of pharmaceuticals to patients
- accelerated drug registration process.

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Nearly three quarters of respondents thought that new categories of medicines would appear on the market in the next two years. They reported that the new medicines used in cancer treatment stood the greatest chance of being introduced to the market (nearly one half of responses). The respondents primarily mentioned target treatment, hence this category partly overlaps with the category of biotechnological medicines (e.g. monoclonal antibodies), which was specifically mentioned by respondents as well.

Categories of pharmaceuticals which can appear on pharmaceutical market in Poland in the next two years

<table>
<thead>
<tr>
<th>Category</th>
<th>Respondents (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Antineoplastic pharmaceuticals</td>
<td>47%</td>
</tr>
<tr>
<td>Biotechnological pharmaceuticals</td>
<td>11%</td>
</tr>
<tr>
<td>Dietary supplements</td>
<td>9%</td>
</tr>
<tr>
<td>Immunological and auto-immunological preparations, vaccines</td>
<td>9%</td>
</tr>
<tr>
<td>Weight-loss preparations</td>
<td>6%</td>
</tr>
<tr>
<td>Dermocosmetics</td>
<td>6%</td>
</tr>
<tr>
<td>Innovative pharmaceuticals</td>
<td>6%</td>
</tr>
</tbody>
</table>

N=53. Based on answers of respondents who claim that new categories of pharmaceuticals will appear on the market; missing data and ‘don’t know’ excluded. The question was open-ended, hence some categories overlap.

Source: KPMG, PMR Research, 2009

Some of the respondents also mentioned new dietary supplements (non-drugs), immunological and auto-immunological medicines and vaccines (especially against influenza or new diseases), as well as weight-loss medications.

From time to time, respondents also mentioned the following types of products:

- dermocosmetics, also in microdoses (non-drugs)
- medicines based on new substances, innovative pharmaceuticals
- pharmaceuticals applied to sensory organ diseases (e.g. ophthalmic drugs)
- generic drugs
- drugs used to treat respiratory illnesses (e.g. asthma)
- drugs used in the treatment of diabetes
- functional food (non-drugs).
Survey respondents indicated that in the coming two years the most promising groups of pharmaceuticals in terms of sales growth among the medicines already present on the market would include antineoplastic and immunomodulating agents, as well as drugs used in the treatment of cardiovascular diseases (according to the ATC system). Over one half of the respondents claimed that sales growth for each of these drug categories would be higher than the overall market growth. Furthermore, 37% of respondents indicated growth in medicines used to treat alimentary tract and metabolic diseases, and one quarter mentioned drugs used in the treatment of illnesses of the central nervous system.

### ATC pharmaceutical categories whose sales growth will be higher than growth of the market as a whole in the next two years

<table>
<thead>
<tr>
<th>Category</th>
<th>Growth Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Antineoplastic and immunomodulating agents</td>
<td>63%</td>
</tr>
<tr>
<td>Cardiovascular system</td>
<td>52%</td>
</tr>
<tr>
<td>Alimentary tract and metabolism</td>
<td>37%</td>
</tr>
<tr>
<td>Central nervous system</td>
<td>27%</td>
</tr>
<tr>
<td>Respiratory system</td>
<td>16%</td>
</tr>
<tr>
<td>Anti-infectives</td>
<td>14%</td>
</tr>
<tr>
<td>Dermatology pharmacisal</td>
<td>11%</td>
</tr>
<tr>
<td>Blood and blood forming organs</td>
<td>8%</td>
</tr>
<tr>
<td>Genito-urinary system</td>
<td>7%</td>
</tr>
<tr>
<td>Endocrinology excluding sex hormones</td>
<td>5%</td>
</tr>
<tr>
<td>Sensory organs</td>
<td>4%</td>
</tr>
<tr>
<td>Muscular and skeletal system</td>
<td>1%</td>
</tr>
</tbody>
</table>

*In terms of sales growth, oncological drugs and immunomodulators were the most promising groups among drugs already available on the market.*

N=75. Respondents were allowed to choose more than one answer.
Source: KPMG, PMR Research, 2009

In our survey, the respondents were also asked which drugs were most likely to make the switch from prescription drugs (Rx) to over the counter drugs (OTC).

The largest proportion of interviewees believed that medicines used in alimentary tract and metabolic diseases would be the first to make the switch, the majority of which would be weight-loss products (a quarter of responses in this group).
The respondents also mentioned statines used in metabolic diseases, proton-pump inhibitors used in gastroenterology, stomach protective drugs, anti-ulcer medicines and drugs used in diabetes. Another frequently-mentioned group of medicines included pharmaceuticals used in cardiovascular diseases (mainly cardiological drugs), medications used to lower cholesterol and blood pressure (e.g. statines) and platelet inhibitors. Additionally, the respondents mentioned anti-allergy products (16%). One in nine respondents indicated drugs used in respiratory system illnesses (mucolitic agents, drugs used in the treatment of asthma and colds). The dermatologic medicines, statines (the group containing responses regarding various applications) and various products used in the treatment of illnesses to do with the central nervous system (sedatives and anti-anxiety medicines) each garnered 9% of all responses.
Predicted effect of changes in regulations of the pharmaceutical market

We asked the respondents about their predictions on the impact of certain intended changes in the regulations on pharmaceutical manufacturers and distributors, pharmacy owners and patients. In particular, we were interested in the two most controversial provisions which the Ministry of Health plans to include in the amended Pharmaceutical Law. One of them concerns the introduction of fixed margins on reimbursed drugs. As a result of these changes, wholesalers and pharmacies will not be able to reduce the maximum margin on subsidized drugs (both wholesale and retail margins) as freely as they have done before now. Under the proposed change, reimbursed pharmaceuticals will be offered at the same price at all pharmacies.
Assessment of impact of the planned introduction of fixed margins and prices of reimbursed pharmaceuticals on market participants

<table>
<thead>
<tr>
<th></th>
<th>0%</th>
<th>25%</th>
<th>50%</th>
<th>75%</th>
<th>100%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Producers</td>
<td>22%</td>
<td>33%</td>
<td>29%</td>
<td>13%</td>
<td>3%</td>
</tr>
<tr>
<td>Distributors</td>
<td>21%</td>
<td>46%</td>
<td>25%</td>
<td>6%</td>
<td>2%</td>
</tr>
<tr>
<td>Pharmacists</td>
<td>19%</td>
<td>35%</td>
<td>29%</td>
<td>11%</td>
<td>6%</td>
</tr>
<tr>
<td>Patients</td>
<td>23%</td>
<td>15%</td>
<td>20%</td>
<td>31%</td>
<td>11%</td>
</tr>
</tbody>
</table>

- Strongly negative
- Rather negative
- Neither positive nor negative
- Rather positive
- Strongly positive

Introduction of fixed margins and prices on reimbursed drugs is likely to be fairly beneficial for patients and adverse for manufacturers and distributors of pharmaceuticals

N = 63. Missing data and ‘don’t know’ excluded.
Source: KPMG, PMR Research, 2009

Assessment of the impact of the intended introduction of fixed margins and prices of reimbursed medicines varied, depending on the market participants considered. According to respondents, this amendment will be beneficial to patients but it will have an adverse effect on drug distributors.

Furthermore, the Ministry of Health planned to include a more precise definition of anti-concentration rules in the Pharmaceutical Law. Changes made to the amended Pharmaceutical Law in 2004, intended to eliminate wholesale and retail trading by a single company, were far from precise and could be evaded. Additionally, the provision limiting the number of pharmacies owned by a single company or related companies to 1% of pharmacies in a single voivodship (province) was not always enforced. Hence, in one of its proposals, the legislature introduced a range of provisions specifying the terms and conditions to be met to obtain approvals to operate a pharmacy or pharmaceutical wholesale business. Under the new regulations, the approval to operate a pharmacy will not be granted if a company (or its direct or indirect subsidiary, or member of the same group) is simultaneously engaged in wholesaling of medicinal product or has applied for such license. Further, a license for operating a pharmacy will not be granted to a company (or its direct or indirect subsidiary, or member of the same group) which already runs 1% of pharmacies in a given voivodship.
Assessment of impact of the planned introduction of precise definition of anti-concentration rules on market participants

More than 50% of the respondents think that the proposed stricter regulation of anti-concentration rules will be the least felt by manufacturers of pharmaceuticals, as it will be neither beneficial nor harmful to them. The most striking difference of opinion was reported concerning the impact of the reform on patients: similar proportions of respondents claimed that the new regulation will be either favorable or negative to the situation of patients. However, the responses provided by our interviewees were more definite in the case of the adverse impact on pharmacists. Actually, the new regulation will exert a negative effect on pharmacy chains but it will positively change the situation of pharmacies operated by individual pharmacists.

In connection with the transitional period under the Accession Treaty, marketing authorization holder interested in extending the validity of their marketing authorizations for medicinal products effective in Poland were required to adjust all documentation regarding medicinal products admitted to trading in line with the provisions of the Pharmaceutical Law transposing EU regulations into the Polish law (i.e. to harmonize documentation) by 31 December 2008. The entire process was completed by the end of 2008 and pharmaceuticals which did not undergo the harmonization procedure (2,800 products) will disappear from the market after their stock has run out (within up to five years). However, the Ministry of Health has not published a detailed list of the products to be removed from the market, thus our survey queried pharmaceutical companies as to how drug harmonization affected their recorded sales figures.
Assessment of impact of withdrawing pharmaceuticals from production due to failure to undergo harmonization on sales results in 2009-2011

N=73. Missing data and ‘don’t know’ excluded.
Source: KPMG, PMR Research, 2009

Most companies which were forced to phase out some pharmaceuticals claimed this step would not affect their sales at all

Forty-five percent of the respondents stated that all their drugs successfully completed the harmonization process. Over one third of the companies which were forced to cease production of some medicines claimed that this decision would not have any bearing on the value of their sales, and only one company expected a significant decline in the value of sales. Thus, it appears that in line with the assurances given by the Ministry of Health, non-harmonized products are predominantly those which generate low sales for pharmaceutical companies. Therefore, one may conclude that withdrawal of these products will not have any major impact on the market’s growth.

In a short while, a considerable number of Polish herbal medicines may disappear from the market as their composition mostly fails to meet the definition set forth in the relevant EU directive. The transitional period for implementing the provisions of that directive in the Polish law (in particular, regarding the adjustment of the documentation of medicinal products authorized for marketing in Poland under the existing regulations) was set for 30 April 2011.
Nearly two thirds of all respondents think that the implementation of the EU directive on the composition of herbal medicines will reduce the volumes of herbal medicines manufactured in Poland. Some respondents (10%) were of the opinion that adoption of these regulations may increase the volumes of herbal medicinal products manufactured in Poland while the remaining interviewees thought it would have no impact on their business.
Development of distribution channels on the pharmaceutical market

Among distribution channels (other than traditional pharmacies), the online channel has been gaining significance. Direct distribution is another other distribution channel likely to grow dynamically in the next 12 months.

Assessment of sales growth in individual distribution channels compared to the market as a whole in the next 12 months

- **Online pharmacies**: 11% faster, 9% same, 80% slower than market
- **Direct distribution**: 13% faster, 28% same, 59% slower than market
- **Online stores**: 19% faster, 30% same, 51% slower than market
- **General stores**: 18% faster, 41% same, 41% slower than market
- **Exclusive distribution**: 28% faster, 44% same, 28% slower than market
- **Herbal and medical stores**: 27% faster, 49% same, 24% slower than market

N=75 for the category of Online pharmacies.
N=68 for the category of Direct distribution.
N=70 for the category of Online stores.
N=71 for the category of General stores.
N=68 for the category of Exclusive distribution.
N=70 for the category of Herbal and medical stores.
Missing data and ‘don’t know’ excluded.
Source: KPMG, PMR Research, 2009
Our respondents indicated that online pharmacies would be the most rapidly-growing channel in the next 12 months. A whopping 80% of respondents predict that distribution through online pharmacies will grow more quickly than the pharmaceutical market as a whole. It is also important to note that over one half of the respondents believe that the sale of pharmaceuticals by other types of online vendors will grow faster than the market as a whole. This means that companies expect continued growth in illegal trade of pharmaceuticals in Poland in the very near future (for companies other than online pharmacies it is illegal to sell pharmaceuticals online in Poland; additionally, the bulk of products distributed in this way are fake). Moreover, the respondents also expect that the role of direct sales will gain significance as well – almost 60% of the companies surveyed expect the growth of this type of sales (which does not include wholesalers as owners of products) to outstrip the growth of the market as a whole. Our respondents said that distribution through herbal and medical stores and exclusive distribution (sale of medicines through a single selected entity) would be the two channels to develop at the slowest rate. In both cases, 27% of respondents believed that these channels would grow more slowly than the market as a whole.

### Introduction of new drugs to the market

Before discussing pharmaceutical companies’ plans regarding introduction of new drugs to the market, let us look at the number of pharmaceuticals currently being offered by the surveyed companies.

#### Number of drugs offered by pharmaceutical companies as at the end of 2008

- $<9$: 28%
- $10-29$: 28%
- $30-99$: 31%
- $>100$: 12%

On average, the surveyed companies offer 64 pharmaceuticals

N=74. Missing data and ‘don’t know’ excluded.

Source: KPMG, PMR Research, 2009
On average, Polish pharmaceutical companies offer 64 medicinal products. Over a quarter of the surveyed companies have fewer than nine pharmaceuticals on offer while the same proportion of pharmaceutical enterprises offers 10-29 pharmaceuticals. A tepid 12% of the respondents offer more than 100 products. The companies covered in the study intend to launch slightly more than three new products by the end of 2009, on average.

Number of new drugs planned to be introduced to market by pharmaceutical companies by the end of 2009

- None: 29%
- 1 or 2: 26%
- 3-10: 40%
- >10: 5%

N=65. Missing data and ‘don’t know’ excluded.
Source: KPMG, PMR Research, 2009

More than a quarter of the companies surveyed did not plan to deliver any new products to the market in the remaining months of 2009, whereas only 5% intended to market more than 10 new medicines. The intention of introducing one or two new medicinal products within this year was expressed by approximately one quarter of the responding companies, while the remaining respondents (40%) planned to launch 3-10 new medicines by the end of 2009. Generally, the surveyed companies intend to launch an average number of just over three new products by the end of this year.
In July 2009, the majority of the representatives of pharmaceutical companies provided optimistic assessments of the financial standing of their companies. Sixty-two percent of respondents described their companies’ financial situation as good, while 12% were of the opinion that it was very good. One fifth of the respondents claimed that the current situation of their enterprise was neither good nor bad. Notably, one out of every 20 pharmaceutical companies surveyed considered their financial standing to be bad. No respondent assessed their financial standing as very bad.

Assessment of current financial situation of companies relative to the year before

N=73. Missing data and ‘don’t know’ excluded.
Source: KPMG, PMR Research, 2009
When considering the previous year, a quarter of our respondents said the financial situation of their businesses had deteriorated, but 40% admitted that there was little change in terms of financial standing versus the previous year. One in 20 companies found themselves to be significantly better-off financially than they had been a year ago, whereas 29% of respondents claimed that the financial standing of their company is rather better-off.

Predictions about financial standing of companies at the end of 2009 relative to the end of 2008

<table>
<thead>
<tr>
<th>Prediction</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rather better-off</td>
<td>48%</td>
</tr>
<tr>
<td>Definitely better-off</td>
<td>8%</td>
</tr>
<tr>
<td>Definitely worse-off</td>
<td>3%</td>
</tr>
<tr>
<td>Slightly worse</td>
<td>19%</td>
</tr>
<tr>
<td>Neither better nor worse</td>
<td>22%</td>
</tr>
</tbody>
</table>

N=73. Missing data and ‘don’t know’ excluded.
Source: KPMG, PMR Research, 2009

The respondents were moderately optimistic about their projected financial situation at the end of 2009, as compared to the year before. Over one half of the surveyed companies anticipated that the financial situation of their enterprises would improve. However, 22% of the respondents did not anticipate any major change. Rather, the same proportion of the respondents was more inclined to expect deterioration in the overall financial standing of their companies.
Actions taken by pharmaceutical companies to address the current economic situation

In our study we asked the respondents about measures taken in response to the global economic crisis, and the impact of the overall situation on capital expenditure at their companies in selected areas of business.

Actions taken or planned by pharmaceutical companies as a result of economic crisis

- No action taken: 43%
- Optimisation of all costs: 34%
- Reduction of marketing and advertising expense: 18%
- Workforce reduction: 3%
- Other: 10%

N=75. Respondents could choose more than one answer. Source: KPMG, PMR Research, 2009

Forty-three percent of respondents indicated that their companies did not take any specific action to reduce costs in view of the prevailing economic situation. Their stance was related to the aforementioned benign impact of the financial crisis on the pharmaceutical industry. Approximately one third of the companies surveyed looked to streamline costs across all categories, whereas 18% focused on reducing marketing and advertising expenses. However, a mere 3% of the companies surveyed decide to downsize their workforce; additionally, specific individual companies withdrew from certain distribution channels.
Pharmaceutical companies do not anticipate any reduction in capex spending in the main areas of business which were covered in the survey. In the case of expenditure on employee development (training, education), over 60% of companies intend to step up such expenditures in the next 12 months. The remaining companies were mostly willing to maintain their current levels of capital outlay. Likewise, approximately 60% of surveyed companies plan to expand investments on production infrastructure (such as plant extension or modernization, the purchase of new equipment, etc.) whereas the remaining companies plan to continue expenses in this area at the previous level. In most cases, spending on human resources and R&D expenditure will remain flat but it should be noted that a sizeable proportion of companies also plan to increase investments in these areas.
Companies from various sectors of the economy take areas of social interest and environmental protection concerns into account when planning their business strategy. Pharmaceutical companies are no different in this regard.

**Corporate social responsibility activities of pharmaceutical companies**

<table>
<thead>
<tr>
<th>Activity</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Charitable activities</td>
<td>46%</td>
</tr>
<tr>
<td>Sponsoring sports and cultural events</td>
<td>20%</td>
</tr>
<tr>
<td>Research seminars and conferences</td>
<td>11%</td>
</tr>
<tr>
<td>Informational campaigns for patients</td>
<td>11%</td>
</tr>
<tr>
<td>Environmental protection investments</td>
<td>8%</td>
</tr>
<tr>
<td>Free clinical trials for patients</td>
<td>5%</td>
</tr>
<tr>
<td>Other</td>
<td>14%</td>
</tr>
<tr>
<td>No actions of this type</td>
<td>32%</td>
</tr>
</tbody>
</table>

N=66. Respondents were allowed to give more than one type of activity; missing data and ‘don’t know’ excluded. Source: KPMG, PMR Research, 2009

However, it appears that approximately one third of the pharmaceutical companies surveyed do not take any actions associated with corporate social responsibility. These companies mainly include smaller enterprises; by way of contrast, all the companies surveyed which employ more than 250 employees do undertake some form of CSR actions. Pharmaceutical manufacturers mostly engage in charitable activities such as financial support for various types of foundations, associations, hospitals and schools. One fifth of the surveyed firms sponsor sports and cultural events. In addition, pharmaceutical companies are quite often involved in the organization of seminars and conferences, and carry out awareness-raising programs designed for patients. They are less commonly involved in activities related to environmental protection projects and do not often arrange for free clinical trial programs for patients. Other activities mentioned included funding grants for talented students, the organization of trade fairs, and training and cooperation with the wider local community.
The pharmaceutical industry in Poland

The overall good condition of the pharmaceutical market was reflected in the financial results posted by pharmaceutical manufacturers. GUS data (official statistics) suggests that the pharmaceutical output sold in 2008 rose by 14.5% year-on-year to PLN 9,784.1m*. The upward trend was continued in H1 2009, with output sold growing by 14.7% relative to the corresponding period for 2008. In all probability, after a weaker 2007 season when the growth of pharmaceutical output sold slackened to 5.3%, the pharmaceutical industry returned to a rapid growth path, and the crisis seems not to have had any major impact on it.

Compared to other industrial segments of the Polish economy, the performance of the pharmaceutical industry is very good. In 2008, compared to the pharmaceutical sector, industrial output sold grew at a significantly slower rate, at a mere 3.5%. Additionally, in H1 2009, industrial output sold declined by 8.3% year on year.

**Pharmaceutical output sold**

Source: KPMG and PMR Research based on GUS data, data for companies with more than 49 employees

* Data for farmaceutical industry and the industry in general comprise companies with more than 49 employees.
Despite a trend to downscale workforce size in industry, the number of people employed at pharmaceutical companies has stayed at more or less the same level. According to GUS data, in 2008 the average employment in the pharmaceutical industry was 23,900, having increased slightly (by 0.8%) since 2007. In H1 2009, the average employment at pharmaceutical companies declined to 23,100, which was still up by 2.3% year on year. Within the same time period, employment at Polish industries fell by 4.9% relative to the previous year.

Employment at pharmaceutical companies

Neither has the crisis negatively impacted pay levels in the pharmaceutical industry. In 2008, the average gross salary paid at pharmaceutical companies was PLN 4,705.4 and increased by 6% year on year. In H1 2009, the average pharmaceutical pay was even higher, reaching PLN 5,368.4, which marks a steep rise of 14.3% relative to the corresponding period for 2008. During the same time period, the average salary in the industrial sector was PLN 3,371.7 (up by 5.1% from H1 2008). The average salary in the pharmaceutical industry is considerably higher than a salary in the chemical, machinery, electronic or automotive industries.
Average gross monthly pay

Source: KPMG and PMR Research based on GUS data, data for companies with more than 49 employees

Labor productivity (value of output sold per employee in PLN ‘000)

Source: KPMG and PMR Research based on GUS data, data for companies with more than 49 employees

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A substantial increase in output sold accompanied by a moderate rise in employment reported in recent years were contributing factors to the significant growth in pharmaceutical industry productivity. In 2008, the amount of output sold per employee in the pharmaceutical industry was PLN 409,400 (up by 15% from 2007). Compared to the figure of PLN 351,500 for other segments of the industrial sector in Poland, this number is high but is still lower than that for the oil, automotive or chemical industries.

### Average gross monthly salary (PLN) in pharmaceutical industry compared to selected industry sectors, H1 2009

<table>
<thead>
<tr>
<th>Industry Type</th>
<th>Average Salary (PLN)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Production of coke and refined oil products</td>
<td>5408.16</td>
</tr>
<tr>
<td>Production of tobacco products</td>
<td>5405.50</td>
</tr>
<tr>
<td>Production of pharmaceutical products</td>
<td>5368.37</td>
</tr>
<tr>
<td>Production and supply of electricity, gas and hot water</td>
<td>4826.27</td>
</tr>
<tr>
<td>Production of beverages</td>
<td>4743.79</td>
</tr>
<tr>
<td>Production of chemical products</td>
<td>3926.50</td>
</tr>
<tr>
<td>Production of paper and paper products</td>
<td>3454.69</td>
</tr>
<tr>
<td>Production of vehicles, trailers and semi-trailers</td>
<td>3235.49</td>
</tr>
<tr>
<td>Production of plant and equipment</td>
<td>3306.47</td>
</tr>
<tr>
<td>Production of computers, electronic and optical products</td>
<td>3104.89</td>
</tr>
<tr>
<td>Production of electric products</td>
<td>3058.34</td>
</tr>
<tr>
<td>Production of rubber and plastic products</td>
<td>2929.63</td>
</tr>
<tr>
<td>Production of food</td>
<td>2731.71</td>
</tr>
<tr>
<td>Production of textile products</td>
<td>2169.61</td>
</tr>
</tbody>
</table>

Source: KPMG and PMR Research based on GUS data, data for companies with more than 49 employees.
Summary
Prospects for development in the Polish pharmaceutical industry

In 2008 the pharmaceutical market in Poland was worth PLN 24.1bn, which represented 11.5% growth in comparison with that achieved in 2007. In 2008, the pharmaceutical market did not feel the impact of the financial crisis. Furthermore, **2008 was one of the best years for the pharmaceutical industry in the last decade**, in part because of high GDP growth and related increases in the purchasing power of Polish consumers. Non-refunded OTC products, with dietary supplements at the helm, drove market growth. As a consequence, in 2008 OTC products already represented 34% of the overall pharmacy market in Poland, whereas in 2005 they accounted for around 30%. Close to half of 2008’s market value was, however, generated by sales of prescription preparations subject to reimbursement.

Furthermore, growth prospects for the pharmaceutical market in 2009-2011 look good: **CAGR (Compound Annual Growth Rate) projected for the sector is 7.4%**.
According to AESGP data, the Polish pharmaceutical market ranks sixth in Europe in sales value, while in terms of sales growth rate (expressed in euro) it is the second fastest growing market, outperformed only by Spain but ahead of all the other EU countries included in the comparison. In 2008, the sector expanded by 17.7% as compared to the year before, whereas the average growth rate for the EU pharmaceutical market was a mere 3.7%.

European pharmaceutical market in 2007-2008 at retail prices (EUR m)

On the one hand, it could be assumed that the financial crisis would have the strongest impact on OTC sales. These products are not refunded and are frequently used only in addition to treatment, hence patients tend to give them up first. However, it should be noted that many products, especially those in the segment of dietary supplements and dermocosmetics, are high-end medications purchased by customers who are not threatened with a reduction in their income. H1 2009 proved that the latter scenario was, indeed, the case. Sales of OTC drugs were also stimulated by a large number of illnesses and infections in Poland. By contrast, the level of sales of prescription drugs is not so much subject to the laws of the market because it is linked to changes made to the list of reimbursed medicinal products by the Polish Ministry of Health. Relatively high resistance of the pharmaceutical industry to the global economic crisis is also demonstrated by the results of our study, and good sales in pharmacies for Q1 2009. In 2010 and 2011, we should expect a gradual increase in the pace of the market value growth.

Also, in the long run, prospects for the pharmaceutical sector are positive. Development of this market will be underpinned by per capita sales of pharmaceuticals that are still lower than in Western countries, which, combined with a tendency to smooth out the differences in per capita income levels, will lead to an equalization of expenditure on medicines. Another factor contributing to the increase in the sector will be the progressive ageing of the Polish population: a growing segment of senior citizens, whose numerous diseases are often treated simultaneously, will create a greater demand for pharmaceuticals.
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- Brand awareness and image research
- Segmentation, distribution and competition research
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- Competences in preparing macroeconomic forecasts
- Expertise in the construction, IT, telecommunications, pharmaceutical, retail and FMCG markets, and knowledge of the markets in Central and Eastern Europe
- Extensive research and consulting experience and numerous personal contacts in many markets
- A broad, wide-ranging offering comprising completed publications + market research and consulting services tailored to individual client needs.
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The KPMG member firm in Poland opened in 1990. Currently, the Polish practice has a staff of close to 1,300 professionals working in Warsaw, Kraków, Poznań, Wrocław, Gdańsk and Katowice.

KPMG has a dedicated pharmaceuticals team which operates at both the international and national levels. It supports clients in creating effective growth strategies and introducing organizational, process and technological changes. KPMG supports pharmaceutical companies in identifying and managing legal*, tax, business and technology risks and in tackling the growing challenge of the regulatory environment. Supported by extensive experience and knowledge of specific needs of the pharmaceutical industry, our interdisciplinary team can offer the exceptional approaches relying on the best industry practices of KPMG offices in Poland and worldwide.

Services offered by KPMG to the pharmaceutical sector:

- Implementation of new structures and business models for pharmaceutical companies (business remodeling, distribution chains, allocation of distribution and marketing functions within a group)
- Comprehensive legal* and tax advisory regarding normative regulations applicable to trading in medicinal products, including issues concerning rights to medicinal products, registration and admission of medicinal products to trading, monitoring of the safety of medicinal products, policies regarding pricing, reimbursement of medicinal products, margins realized at the individual levels of the distribution chain
- Advisory in carrying out clinical research and identifying tax opportunities to support innovation and development projects in Poland
- Advice to pharmaceutical companies on tax settlements with a view to ensuring compliance with the applicable regulations and helping to reduce the effective tax rate
- Incorporation of foreign entities from the pharmaceutical sector for tax purposes and providing tax advisory services to such companies
- Developing optimization strategies to pharmaceutical companies, including tax optimization in supply chain management
- Developing tax-efficient tools consistent with the effective regulations to support sales of medicinal products to healthcare institutions, pharmacies and wholesalers
- Tax and regulatory analysis regarding direct distribution of pharmaceuticals
- Preparation of business risk maps for pharmaceutical companies
- Compliance analysis of advertising and promotional activities carried out by pharmaceutical companies with the requirements of pharmaceutical law; identification of risk areas; suggestions for elimination and modification in order to ensure regulatory compliance
- Developing marketing procedures in the form of internal regulations for sales and marketing departments so as to ensure compliance of promotional and marketing activities with the provisions of the law and the business codes of conduct
- Preparing tax documentation for transactions with related parties – issues related to profit calculation
- Benchmarking analysis to determine or verify settlement rules for drug imports, clinical research monitoring and promotional and marketing services
- Negotiation of advanced pricing agreements (APA)
- Participation in tax and customs proceedings and representing pharmaceutical companies in connection with conducted proceedings.

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