countries, and the Czech Republic is no exception. The percentage of children under the age of 16 is decreasing while the percentage of those aged 65 or older is increasing. The percentage of the population over 64 exceeded that of children for the first time in 2006. The ageing population is a result of not only low birth rates and mortality but also increasing life expectancy. In 2010, life expectancy reached 74.4 years for men and 80.6 years for women. These factors are causing higher governmental healthcare and social expenditure, which are leading to budget imbalances and deeper deficits.

HEALTHCARE SYSTEM
Since the early 1990s, the Czech Republic has had a system of social health insurance (SHI) based on compulsory membership of one of several insurance funds. SHI contributions are obligatory and based on wage levels. The contributions are collected from employers, employees and self-employed by the insurance funds. At the time of writing, SHI contributions are administered by nine health insurance funds, the largest of which is VZP (the General Insurance Company), which covered 63 per cent of the total insured population at the end of 2007.

The healthcare system is mostly publicly-financed. In 2008, only 15.3 per cent of all healthcare expenditure was from private sources, according to the World Health Organisation (WHO). By contrast, the share of private sector expenditure in the EU on healthcare as a percentage of total healthcare expenditure is 23.44 per cent.

The country also falls below the EU average in the share of total healthcare expenditure as a percentage of GDP (8.2 per cent in the Czech Republic, 9.88 per cent EU average in 2009). Currently, efforts are being made to increase the share of private expenditure on the total healthcare expenditure.

The financial instability of the Czech healthcare system has led to many reforms in the last year or so. Because of an inappropriately high demand for free-of-charge inpatient and outpatient healthcare services, flat user fees were introduced in 2008. A flat fee of 30 Czech korunas (CZK) was imposed on doctor visits and prescription pharmaceuticals, a fee of CZK 60 per day in hospital and a fee of CZK 90 on the use of ambulatory services (A&E) outside standard
office hours. Other reforms focused on the issue of hospital ownership in terms of privatisation and management structures and on compliance with EU law.

As in many other developing countries, lifestyle diseases are becoming increasingly common. Diseases of the circulatory system are the most frequent cause of death in the Czech Republic, along with malignant neoplasm and respiratory diseases.

The flat fee introduced in 2008 significantly reduced overconsumption of outpatient treatments. To illustrate this, in 2007, GP surgeries, which have more than 7.92 million adult patients on their books, reported 46.7 million hospital outpatient treatments. Two years later, in 2009, these surgeries carried out 38.6 million examinations among their 7.9 million registered patients by the end of the year.

The Czech Republic retains pole position among all OECD countries for consumption of medicines for treating high blood pressure. An upward trend in expenditure is accompanied by a decrease in number of packages sold.

Distributed medicines account for about 28 per cent of total healthcare expenditure and this figure remains relatively stable. Of these, in 2010, 83 per cent were prescription drugs and 17 per cent over-the-counter (OTC) medicines. This proportion is relatively constant, too.

**PHARMACEUTICAL MARKET**

The Czech pharmaceutical market is the third largest in the CEE region and has grown fast in recent years. In 2009, $4.7bn in pharmaceuticals were sold there. In 2010, however, the market was significantly impacted by 7 per cent cuts in maximum regulated medicine prices, which were introduced as a part of the government’s austerity measures. In 2011, the government is applying a similar scheme, but this affects only a certain part of all drugs sold.

The market was affected in 2008 too, when mandatory fees for medical prescriptions were introduced. These fees led to decreased demand, with revenues in constant prices declining by 5.7 per cent year-on-year.

Czech manufacturers offer only a limited range of drugs. As a result, the pharmaceutical industry ranks among the sectors with the highest deficit in foreign trade. In 2007, exports were worth €812m and imports €2.2bn, creating a deficit in excess of €1.4bn. Germany is the Czech Republic’s most important foreign trade partner.

Foreign producers dominate the market, with a 93 per cent market share. The largest among these is Sanofi. The largest Czech pharma producers that are not owned by multi-nationals are Walmark and PRO.MED.CS. Walmark ($144m sales) focuses on vitamins and dietary supplements and has sales subsidiaries in seven CEE countries plus France. PRO.MED.CS ($579m sales) produces a wide portfolio of both OTC and prescription drugs.

Sanofi has become a leader in the Czech market since acquiring Zentiva. Sanofi became the largest shareholder in Zentiva in 2006 when it took a 24.9 per cent stake in the company. Three years later, Zentiva became part of the Sanofi group. Today, Zentiva is the third-largest and fastest-growing generic company in Europe.

**MARKET ACCESS**

Most foreign companies entered the Czech market by merging with or acquiring already existing companies. The most important mergers and acquisitions in recent history are:

- In 2006, the IVAX Corporation was integrated into Teva
- In 2007, the Italian Angelini Group acquired Medicom International
- Also in 2007, Glenmark Pharmaceuticals bought more than 90 per cent of the shares in the pharmaceutical company Medicamenta
- In 2008, Pliva-Lachema, part of Barr Pharmaceuticals, was bought by Teva.
After the Velvet Revolution in 1989, when the Czech Republic returned to liberal democracy, the general lack of a market led to a boom in the establishment of new businesses. It was during this boom that today’s largest exclusively Czech pharmaceutical producers – PRO.MED.CS and Walmark – were established.

PRO.MED.CS is a mid-sized company operating not only in the Czech Republic but also in the Central-Eastern European markets and in central Asia. The company is export-orientated, with exports accounting for 73 per cent of its turnover.

Walmark originally traded in agriculture products. In 1992, the company began to import and subsequently produce pharmaceuticals, particularly food supplements and healing cosmetics. Today, Walmark holds the top position in the dietary supplements segment in the CEE region. The company has subsidiaries in Slovakia, Romania, Poland, Hungary, Bulgaria, Latvia, Lithuania and France. It exports to south-east Europe and Asia.

Owing to the mergers and acquisitions mentioned above, the reason for the low share of domestic producers is obvious: the local market has been subsumed by the large multinationals. For example, Zentiva, one of the best known local drug producers, is owned by Sanofi and controls 17.5 per cent of total sales.

There is no doubt that high consumption of pharmaceuticals in the Czech Republic is an attractive reason for entering the Czech market. On the other hand, harsh price control results in lower profit margins than in many other EU member states and, according to the government’s promises, this trend will continue.

**CZECH PHARMA MARKET – TOP PLAYERS**

<table>
<thead>
<tr>
<th>Company</th>
<th>Sales, $m</th>
<th>Market share</th>
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<tbody>
<tr>
<td>Sanofi</td>
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<tr>
<td>GSK</td>
<td>364</td>
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<tr>
<td>Pfizer</td>
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<td>6.5%</td>
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<tr>
<td>Roche</td>
<td>293</td>
<td>6.3%</td>
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<tr>
<td>Novartis</td>
<td>211</td>
<td>4.5%</td>
</tr>
<tr>
<td>Teva</td>
<td>199</td>
<td>4.3%</td>
</tr>
<tr>
<td>Boehringer Ingelheim</td>
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<td>2.5%</td>
</tr>
<tr>
<td>Merck</td>
<td>76</td>
<td>1.6%</td>
</tr>
<tr>
<td>Medicon International</td>
<td>64</td>
<td>1.4%</td>
</tr>
<tr>
<td>Bristol-Meyers</td>
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<td>0.8%</td>
</tr>
<tr>
<td>Glenmark</td>
<td>23</td>
<td>0.5%</td>
</tr>
<tr>
<td>Pharamceuticals</td>
<td>21</td>
<td>0.5%</td>
</tr>
<tr>
<td>PRO.MED.CS Praha</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Sources: Annual reports, Creditinfo, press search (shares are indicative)

**REGULATION**

The main regulatory body in the Czech Republic is the State Institute for Drug Control (SÚKL). It is responsible for registering new pharmaceuticals and for setting pricing and reimbursement levels. The Ministry of Health is responsible for proposing new laws and dealing with appeals against SÚKL decisions. Since the Czech Republic joined the EU in 2004, its regulations have had to conform to EU law.

Regulation covers not only pricing but also pharmaceutical companies, which have to follow other rules with respect to applying for distribution or production licences, advertising, provision of samples and co-operation with physicians.

Regulation of promotion of medicines is rather complex. Any advertising broadcast by radio and television is under the supervision of the Council for Radio and TV Broadcasting (RRTV). Supervision of advertising in other media is divided among several institutions. Advertising for pharmaceutical products is supervised by SÚKL, while advertising for healthcare is supervised by the Ministry of Health. Advertising expenses reached more than CZK1bn (more than €40m) in the first half of this year, an increase of 19 per cent compared to the previous year.

Czech law also regulates pharmaceutical companies’ rewards to specialists to make sure drugmakers are not exercising excessive influence on specialists’ decisions in choosing which medicines to prescribe. A pharmaceutical company cannot give a specialist more than CZK1,500 (€60) in gifts or provisions per year, and such rewards must be related to the specialist’s professional activity.

A similar problem arises regarding rewarding hospitals and doctors for buying facilities or preferring certain kinds of drugs. In addition, there is the issue of companies sponsoring doctors’ further education at congresses or other special training events abroad.

**OTC MARKET**

The over-the-counter (OTC) market in the Czech Republic ranks as one of the most attractive and liberal among CEE countries. According to Business Monitor International (BMI), it was worth CZK13.4bn ($709m) in 2010 and has been growing at a similar rate to the overall market over the past few years. A 4.05 per cent compound annual growth rate is forecast for the period between 2010 and 2015. The growth is supported by changes in lifestyle. People are taking greater care of their health and appearance by buying bio-products, beauty products and supplements such as vitamins and herbs.

The OTC sector is not under SÚKL’s pricing control and is less exposed to healthcare reforms than prescription medicines. This advantage is becoming more important in times of pricing reforms. Today, the OTC drug market accounts for 16.7 per cent of total pharmacy sales.

Online sales of OTC medicines have been allowed since 2006, but only pharmacies licensed by SÚKL can provide this service. There are currently 158 pharmacies selling OTC products online in SÚKL’s database; in mid-2007, there were only 74.

The Czech OTC market is fairly concentrated, with the top three players holding 50.1 per cent of the total market by value. The leader is Johnson & Johnson (J&J), with 21.4 per cent. The global leader, J&J, entered the Czech market in 1991.

**PRICING AND REIMBURSEMENT**

As the Czech Republic is a member of the EU, the pricing and reimbursement process must be aligned with Council Directive 89/105/ EEC. Since 2008, SÚKL has been responsible for pricing and reimbursement decisions. Prior to that, it was the Ministry of Health.

In general, SÚKL sets either a maximum price or a maximum margin on healthcare products, where the maximum price is set as the average production price of the three lowest prices of the same pharmaceutical in eight reference countries (Estonia, France, Italy, Lithuania, Hungary, Portugal, Greece and Spain). The maximum price must be updated every two years. In 2010, the maximum prices of pharmaceuticals were temporarily decreased by 7 per cent as a part of overall cost saving measures. One year later, in 2011, the same scheme was extended to the pricing of pharmaceuticals that had not been updated since January 2008.

Reimbursement levels are based on a reference principle or set
as a percentage of maximum price, under the condition that at least one pharmaceutical in each reference group must be fully reimbursed. Special rules apply to treatments for serious diseases – for example, cancer – which are fully reimbursed, as well as for highly innovative medicines, which can be reimbursed under more favourable conditions.

The Ministry of Health plans to change the law covering pricing and reimbursement rules. The maximum price would be determined as the average of the three lowest prices in 21 EU countries instead of eight countries, which could decrease medicine prices by up to 30 per cent. Reimbursement levels would be set at 75 per cent of the lowest maximum drug price in each reference group.

Another aspect of the plan is a simplification of the revision procedure, which would mean timely updates and thus regular price decreases on pharmaceuticals. There would also be restrictions on innovative medicine reimbursement. Currently, reimbursement in one reference country is a sufficient condition for reimbursement in the Czech Republic. However, the Ministry of Health wants to increase the obligatory number of reference countries to three.

The maximum price set by SÚKL is not the final price which the customer pays. Rather, it is the maximum price for which a manufacturer can deliver a drug to the Czech Republic. The price is then increased by a margin and VAT. The margin is also regulated and is divided between the pharmacy and the distributor.

RESEARCH AND DEVELOPMENT

Research and development (R&D) expenditure in the Czech Republic in 2008 as a percentage of GDP was 1.47 per cent, according to the European Federation of Pharmaceutical Industries and Associations (EFPIA). This is slightly less than the EU average (1.59 per cent). Comparing R&D expenditure in CEE countries, the Czech Republic is performing well. In Hungary, the share is one per cent of GDP, in Poland 0.61 per cent and in Slovakia 0.47 per cent. EFPIA also reported that, while new drugs result from many years of research, verification and approval, revenues fully cover the costs of R&D in only three out of ten new products. High costs lead to high prices of newly invented drugs.

“A portion of the grant, $10m, goes to the Mayo Clinic and is believed to mark the first time a US research institution has received a significant portion of a major EU grant”

In 2011, St. Anne’s University Hospital in Brno together with the Mayo Clinic, a US-based organisation focused on medical care, research and education, received a $220m grant to support their collaboration in clinical research and education at the International Clinical Research Center (ICRC), which is now under construction in Brno and scheduled to become operational in autumn 2012. The ICRC-Mayo application for EU funds received the highest rating among all entries in terms of scientific quality. A portion of the grant, $10m, goes to the Mayo Clinic and is believed to mark the first time a US research institution has received a significant portion of a major EU grant.

The Czech Republic has a tradition of research in new medicines, thanks in particular to Prof Antonín Holý, who specialises in chemistry. He co-operated on the development of several important antiretroviral drugs and was involved in the creation of the most powerful drug in the treatment of AIDS. He is the author of more than 400 scientific discoveries and holds 60 patents for medicines such as Vistide (used for the treatment of herpetic eruptions), Viread (AIDS) and Hepsera (hepatitis B). Antivirals from Prof Holý’s laboratory are used in 90 per cent of new cases of HIV-positive patients. Prof Holý is a member of the Institute of Organic Chemistry and Biochemistry of the Academy of Sciences of the Czech Republic (IOCB), which co-operates with US firm Gilead Sciences. Gilead Sciences gives the IOCB $1.1m each year for the research of new medicines.

“In the Czech Republic, generic products dominate in terms of the amount of products sold, but patented drugs perform better in terms of sales.”

This gives rise to a problem between branded and generic pharmacy products. Generics are 30-60 per cent cheaper than branded products, the prices of which reflect the costs of research. In recent years, the patent protection of many originals has expired. Between 2010 and 2012, 133 patented drugs will become available for generic production. In the Czech Republic, generic products dominate in terms of the amount of products sold, but patented drugs perform better in terms of sales.

In order to stimulate R&D activities in the country, companies performing R&D are entitled to a double deduction of eligible costs incurred in respect of R&D from the tax base (for corporate income tax purposes). If the company meets certain requirements, such as its R&D activity having valuable novel elements or it uses specific innovative procedures, it may deduct the full amount of eligible expenses that are incurred in connection with the realisation of R&D projects from its tax base. This means that, in practice, it can claim certain costs twice; once as a tax-deductible expense and once as an item decreasing the tax base (source: Lenka Mrázová, The Future of the Pharmaceutical Industry in the Czech Republic, Czech Chemical and Pharmaceutical Industry, April 2010).

In addition, the Czech Republic, as a member of the EU, provides funding and grants for a broad range of projects and programmes, including the Research and Development for Innovations operational programme, through which many important investments are financed.
CLINICAL STUDIES

Based on the number of applications filed, the Czech Republic is an attractive location for carrying out clinical studies. It has many high quality premises that can conduct clinical trials in compliance with the proper clinical practice and ensure validity and accuracy of the data. Also, in certain diseases, there are enough patients to participate in new drug tests and Czech patients are usually willing to take part.

The sponsor of a clinical study is, in most cases, a foreign or multinational pharmaceutical company which aims to bring the tested drug to market in the future. As elsewhere, in the Czech Republic, international multi-centre studies predominate. Much less common are so-called academic studies, which are sponsored by medical or professional societies and funded, for example, by grants.

Trials in which a completely new substance is administered to humans for the first time are rare; fewer than ten such studies take place in the country each year. This type of study has a very small number of participants generally – about 24 in each study – and they usually receive a financial reward.

Clinical studies conducted on humans (phase I-IV) are strictly regulated in the Czech Republic and are conducted according to set rules. Before the drug is included in a clinical study, it must pass standard preclinical testing involving certain types of animal tests. Then the company must gain the consent of SÚKL, the ethics committee and also the patient on whom the drug will be tested.

The clinical trial approval process is performed independently by SÚKL and at least one ethics committee. For multi-centre clinical studies, it is also necessary to obtain the approval both of the ethics committee and a local ethics committee for each location. The main goal is to evaluate the risk and benefit for patients, the scientific rationale for implementing the study, evaluation of the quality of the medicines used and the likelihood that the study will obtain objective and top quality data and information.

SUPPLY CHAIN

In the Czech Republic, the fairly concentrated manufacturing market is supported by a highly concentrated distribution set-up, where the top four companies account for 96 per cent of the market. The largest, Phoenix, controls almost half the market.

In contrast, the retail market is very fragmented. In 2009, there were about 2,600 pharmacies, or one pharmacy per 4,048 people. Almost all of them are run as private enterprises, but a new trend of establishing pharmacy chains has appeared in recent years. Companies such as Dr Max, Pharmaland and Lloyds are growing fast. For example, the number of Dr Max pharmacies increased from 100 in 2008 to 170 in 2011. Small pharmacies cannot compete with the prices offered by the chains. When the flat user fee of CZK30 per prescription drug was introduced, the pharmacy chains tried to attract customers by refunding them the fee.

In terms of regulation, anyone can own a pharmacy. If the owner is not a pharmacist, the pharmacy must have a professional representative who is a qualified pharmacist.

LEGISLATION

The Czech Republic is now transforming its pension, health and social care system, with many changes taking place each year. Planned healthcare reform is an important issue which could significantly influence the pharmacy industry market. The 2010 Programme Announcement of the Czech government puts healthcare as one of its priorities. The government plans to adopt a set of reforms in order to modernise the healthcare sector and increase its effectiveness.

Some of the planned changes regarding the pricing system...
have been mentioned above. The main point is that the government wants to change the way the system works completely, through introducing positive lists which would give insurers the right to influence the prescription of a particular medicine directly. With the introduction of a generic prescription, doctors would prescribe active substances only, not particular medicines. This proposal has become a hot issue, as pharmacists, who do not necessarily know patients’ health conditions, would be responsible for what medicine to recommend. Following pressure from the Czech Medical Chamber, the Minister for Health of the Czech Republic has abandoned this plan for the time being. The Czech Medical Chamber argues that such a system could be dangerous for patients and that pharmaceutical firms’ focus would only move from doctors to pharmacists and the situation would remain the same.

In 2011 the Chamber of Deputies passed an amendment to the Public Health Insurance Act, known as the first phase of healthcare reform. The amendment raises the hospital-stay fee from CZK60 to CZK100 per day, imposes a charge on medication of up to CZK50, and introduces a single charge for prescriptions of CZK30.

In addition, changes are expected in the management of insurance companies and the market’s competitiveness. Under the proposals, the management and executive councils of insurance funds would have responsibility for the performance of the fund. All funds would be non-profit-making under the financial supervision of a government body and would employ corporate accounting methods. The only way to close an insurance company would be through merger with another health insurance company.

The Czech government would like to increase competition among healthcare facilities and pharmaceuticals. It wants insured people to be sent to a given facility, depending on its price and quality. These facilities would prescribe medicines only if they were on the positive lists of approved pharmaceuticals.

Another important issue is the computerisation of the entire healthcare system. Through remote access, patients could see which medical treatments were written down by the healthcare provider and reimbursed. Simplification and lowering the administrative costs of the civil service are long-term government goals.

SALESFORCE REMUNERATION
Pharmaceutical companies in the Czech Republic traditionally attract and retain their salesforce – including medical/sales representatives, key account managers, sales managers (area/regional/district/national) – through offering competitive total compensation packages consisting of a mixture of base pay, incentives, bonuses and benefits. The target level which pharmaceutical companies use for an external remuneration benchmark for their salesforce is the median of the pharmaceutical market (93 per cent of companies) and the third quartile of the market (seven per cent of companies). Hence the targeted level for the overall market for the sales functions is median (60 per cent), average (32 per cent), first quartile (2 per cent) and third quartile (6 per cent) in the Czech Republic, according to PricewaterhouseCoopers’ PayWell remuneration study.

Hence, pharmaceutical companies in the Czech Republic use the variable pay related to performance based on management by objectives, balanced scorecards or simply by setting objectives for the defined period for the management, or for specialist, supporting and administrative functions. Special incentive schemes to support the achievement of sales targets/sales plans are designed for the salesforce. These targets are set according to the sales cycles (quarterly, four/six-monthly bases) and adjusted according to the phase of the life cycle in which the company launches or relaunches a product, for example. The incentive part of total pay varies from 20 per cent to 35 per cent and is mainly linked to the fulfillment of the sales target, gaining market share, share of voice, product knowledge and some other qualitative components of the incentive, such as the quality of the sales call measured according to pre-defined rules (e.g. preparation, argument, communication style, behaving according to the code of ethics). The important thing for motivation is that the sales plan is achievable and the criteria are known in advance. The base pay is mainly linked to the competence, number of years of experience, knowledge of a specific therapeutic area and level of education.

From the perspective of company benefits, the Czech pharmaceutical industry is typical in its five-week holiday entitlement (100 per cent), pension insurance (82 per cent), life insurance (59 per cent) and accident insurance (47 per cent). Companies support the health of their employees in terms of extended healthcare (47 per cent) and sick day offerings (82 per cent). The company car policy is important for the salesforce as well. Private usage of the company car is common in this industry sector. In total, 22 per cent of companies cover full petrol consumption for their salesforce.

THE FUTURE
The Czech pharmaceutical market grew at an impressive 9 per cent compound annual growth rate between 2007 and 2009 and is forecast to grow six per cent by 2015. Growth is likely to be related to an expected increase in expenditure on pharmaceuticals due to the ageing population, chronic diseases such as obesity and asthma, and increased contributions of the private sector to total healthcare expenditure. Planned changes to the VAT rate could increase pharmaceutical prices moderately, but will probably not have a significant influence on demand. In addition, the future depends on the decisions of the Czech government and changes to the law.

The Authors
Lenka Mrázová (left) is director of PricewaterhouseCoopers Czech Republic and Zdeněk Hrdlička is manager of PricewaterhouseCoopers Czech Republic.

SPENDING ON HEALTHCARE AND PHARMA SALES

<table>
<thead>
<tr>
<th>Year</th>
<th>Pharmaceutical sales – $bn</th>
<th>Pharma sales – % of GDP</th>
<th>Pharma sales – % of healthcare expenditure</th>
<th>Healthcare expenditure – $bn</th>
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<td>1.95</td>
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Source: BMI