UKRAINE ACC
THE CHAMBER OF COMMERCE

VISION 2020:

ROADMAP FOR DEVELOPMENT OF THE PHARMACEUTICAL SECTOR IN UKRAINE

pwc

APRaD
Association of Pharmaceutical Research and Development

Dear colleagues,

We are honoured to present a comprehensive report on the innovative pharmaceutical industry in Ukraine.

This report presents a vision of the future, showing how the health of patients in Ukraine can be advanced with improvements of the efficiency of the healthcare system through development of the pharmaceutical sector.

We base our approach on research that examines how best to strengthen the pharmaceutical industry, offering an analysis of ways to bring Ukraine into the top ranks of leading countries in biopharmaceutical innovation. While much work lies ahead, the report provides an achievable policy road map to guide policy-makers and industry.

Critical to the success of this ambitious strategy is the establishment of effective dialogue between the pharmaceutical industry and the government. This is the indispensable first step. Our road map calls for joint efforts aimed at improving the regulation of the pharmaceutical industry in Ukraine. Agreeing on common goals and implementing policy changes during the next few year will benefit Ukrainian patients and the global competitiveness of the strategic biopharmaceutical sector in the Ukrainian economy.

After many months of in-depth research and analysis, we are confident that that the recommendations of this study provide a solid base for strengthening and developing government-industry cooperation, and that the policies recommended here will improve the health of the citizens and welfare of Ukraine. In the next few pages, we summarize key highlights of our findings.

Bryan Disher,

Chairman of the Board,
American Chamber
of Commerce in Ukraine

Association of Pharmaceutical
Research & Development

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1 EXECUTIVE SUMMARY

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Ukrainian healthcare system development

The government of the Ukraine has made development of healthcare system a priority in order to advance health and improve the quality of life of citizens.

Realizing a critical medical and demographic situation in Ukraine, which is characterized by low fertility compared to the high mortality rate, a negative natural growth and demographic aging, increasing the overall burden of disease and the urgent need of optimization of the health system, not adapted to market environments, the Ukrainian government developed and launched several initiatives with strategic goals, such as:

- Increase the average life expectancy;
- Stabilize and achieve a downward trend in mortality rates (i.e. mortality of people of working age, infant mortality, maternal mortality);
- Increase basic vaccination coverage for children.

The results of all government initiatives, implemented both at the federal and regional levels in parallel with rising healthcare expenditures, are now evident. There were significant advances in diagnostics and treatment of certain diseases, and an overall improvement of the health of citizens in Ukraine.

Between 2001 and 2011, the mortality rate in Ukraine decreased from 15.3 to 14.5 deaths per thousand, and life expectancy at birth increased by 2.5 years. Healthcare refinement in Ukraine is determined by a set of measures which include those aimed at improving the healthcare professionals' skill level, healthcare infrastructure and equipment, and measures to deliver more high-technology medical services among many other interventions.

The role of the innovative pharmaceutical industry in the economy and healthcare

International practice demonstrates that the introduction of innovative drugs drives progress in disease treatment and extends life expectancy. From 2000 to 2009 innovative medicines accounted for 73% of the increase of life expectancy in 30 OECD countries. Patient access to innovative medicines is essential in the treatment of cardiovascular, cancer and other diseases prevalent in Ukraine that are a major cause of death.

The pharmaceutical industry plays an important role in improving public health and makes a significant contribution to the economy. It employs a highly trained workforce, contributes to the state budget through taxes, and creates demand for products from related industries. Development of the pharmaceutical industry also mobilizes a significant amount of foreign direct investment (FDI).

As an example, creation of favorable conditions for the pharmaceutical industry in Singapore brought $17.7 billion dollars in FDI during a 5 year period between 2007—2010.

A special advantage of pharmaceutical industry investment is its high research intensity. This results in a high share of research projects in the total amount of investments — about a third of the FDI in the pharmaceutical industry in Singapore is aimed at research and development.

Research and development projects give countries additional advantages, such as creation of highly-skilled work force and high-tech development.

At the same time, to attract FDI into the pharmaceutical industry-especially with projects related to the transfer of advanced technologies- a favorable investment environment should be established in the country. Our research analysis reveals that the following factors are especially important in determining new investment:

- Favorable conditions to conduct clinical research (trials);
- Efficient and transparent drug registration system;
- Developed and sufficiently financed drug reimbursement system;
- Efficient and transparent IP rights regulations.
- Competitive taxation
- Level playing field for investors vs. local players
- Continuous and structured dialogue between the industry and the government.

Study goals and methodology

Representatives of innovative and generic pharmaceutical companies share and support the goals of the government's healthcare programs. The current study was conducted in order to find additional opportunities to boost the development of the pharmaceutical industry in Ukraine by creating an attractive investment environment, and support the population's access to effective medicines to address unmet medical needs.

According to the goals stated by this project, the research identifies possible actions which could improve both the pharmaceutical industry at all stages from research and development to manufacturing and exports, and patients' access to medicines leading to improved health.

In order to identify critically needed policies and actions, we have conducted interviews with pharmaceutical industry experts and representatives of the government. To assess the current environment from the investors' viewpoint, and to understand possible gaps in perception between industry executives and policy-makers, we have conducted a survey of the Biopharmaceutical Competitiveness Index (BCI).

The BCI is a unique survey tool. Each section of the BCI survey is based on a statistical analysis and estimates the opinion of respondents on the efficiency in different segments of the "eco-system" governing the development of the pharmaceutical industry. Accordingly, the survey begins with addressing the quality of the scientific capabilities and infrastructure and goes on to an analysis of the clinical and manufacturing capabilities, the regulatory environment and market conditions.

Overall, the survey is designed to provide a comprehensive, comparative, relevant and accurate snapshot of a country's performance at different segments of the biomedical value chain, and hence its attractiveness for investment.

On the basis of the analysis conducted, recommendations and a policy road map were developed. These findings serve as a useful guide for officials developing policies that improve access of patients to innovative and high-quality medicines, and the promotion of a globally-competitive innovative biopharmaceutical industry in Ukraine.

Brief study results

The BCI survey finds that the overall score of the Ukrainian pharmaceutical industry was 56 points out of 100, indicating significant potential for improvement of the investment environment compared to other countries. The potential exists in all segments of the factors governing the performance of the pharmaceutical industry, and is especially significant in the segment of healthcare financing and effective drug provision financed from the public sources.

Based on results of the BCI survey, interviews with Ukrainian government representatives and pharmaceutical industry experts, as well as the analysis of global best practices, we have identified the following areas to focus on to improve the competitiveness of the pharmaceutical industry environment. The key points include:

1. Create favorable conditions to conduct clinical research (trials)

- Increase transparency and improve the process of clinical trial authorization:
  - — Ensure professional development of experts who review applications for conduct of clinical trials in line with the international practice;
- Improve access to clinical trials sites:
  - — Simplify the procedure for obtaining permission to and export import drugs, equipment and materials for clinical trials;
  - — Review the legislation requirements for the CTs facilities accreditation and increase number of CTs facilities that are compliant with legislation requirements;
  - — Establish clear financial guidelines on the agreements between CT sponsors and medical institutions
- Introduce economic incentives for clinical trials:
  - — Cancel mandatory certification of equipment imported into Ukraine in order to conduct clinical trials

2. Further increase the efficiency and transparency of the drug registration system

- Introduce recognition of GMP certificate issued by PIC/S1) members without any further confirmation by local authorities required;
- Introduce accelerated procedure of marketing authorization for innovative medicines that have been already registered according to the centralized EU procedure;
- Enforce adherence to the deadlines for drug registration process set by existing law:
  - — Ensure strict adherence to the duration of authorization procedure through establishment of the relevant KPIs for the experts involved in dossier examination;
  - — Introduce specialized trainings for the experts involved in assessment of the application dossier to ensure familiarization with current registration procedures and regulations thus minimize risk of further confusions and delays during the drug approval process;
  - — Increase operating efficiency of the authorization bodies through organizational structure and internal processes improvement;
- Extend validity of the marketing authorization upon first renewal — after one renewal, the marketing authorization shall remain valid for an unlimited period, unless the competent regulatory authority decides otherwise;
- Further development of the requirements to and guidelines on biosimilars evaluation:
  - — Develop clear requirements to and guidelines on pre-clinical and clinical information to be submitted by the applicant for biosimilars registration;
  - — Develop clear requirements to and guidelines on the risk management plan to be submitted by the applicant for a biosimilar registration

3. Further develop and finance sufficiently the drug reimbursement system

- Establish a Joint Task Force to manage the drug reimbursement system development;
- Enforce the financing of the ambulatory drug provision programs provided by the current regulation through introduction of new ambulatory drug reimbursement projects;
- Expand the drug coverage under existing and new drug reimbursement projects:
  - — Introduce a procedure for drug manufacturers to apply for inclusion into the drug reimbursement lists under the pilot projects based on the latest clinical guidelines and assessment by an independent body;
  - — Expand the range of drugs reimbursed under the Anti-hypertension Pilot Project to include new drugs in line with the

latest clinical guidelines and to cover drugs for treatment of the coronary heart disease (starting with Myocardial Infarction as No. 1 priority);

— Introduce and regularly update drug reimbursement lists for ambulatory drug reimbursement projects being launched

- Develop the rules for INN / brand name prescription:

  — Introduce the list of drugs that are to be not considered interchangeable and to be prescribed by brand name including biological products and drugs with the narrow therapeutic index

- Introduce a separate procedure for pricing of original drugs under pilot drug reimbursement projects:

  — Introduce the pricing of original drugs based on the external price referencing to average ex-manufacturer drug price in a limited basket of comparable countries and price negotiations between the MoH and original drug manufacturers;

  — Introduce co-payment system to allow a doctor and a patient to have the right to choose the best suitable treatment;

  — Introduce the pharmacoeconomic evaluation as a part of a pricing procedure for original drugs with the external reference pricing as a supplementary mechanism (Based on EU experience, it is quite important and effective to introduce external reference pricing as an instrument protecting Intellectual Property Rights. Although pharmaeconomic evaluation is used on all pharmaceutical products for which an application for reimbursement submitted. Thus, both instruments may coexist in different spheres of pharma regulation).

- Simplify a procedure for pricing of generic drugs under pilot drug reimbursement projects; develop a separate procedure for pricing of biosimilar drugs (European pharmaceutical systems use several different types of pricing and reimbursement policies for medicines including reimbursable medicines. Generics, if deemed reimbursable, are subject to the same policies. In addition, many countries have implemented specific measures to promote generics uptake, including demand-side measures targeting prescribers, pharmacists and, less frequently, patients. Usually, a mix of policies is employed. The design of these measures can significantly influence generics uptake and the degree of public savings)

- Ensure sufficient financing of the reimbursement programs:

  — Develop mandatory national health insurance system to ensure sufficient financing of the health expenditure including drug reimbursement

- Replace centralized procurement of ambulatory drugs with reimbursement.

4. Modify hospital drug procurement regime

- Ensure sufficient financing of the hospital drug procurement:

  — Consider introduction of separate target budgets for procurement of the certain (I suggest not to use this term as it draws unnecessary attention to prices) drugs;

  — Develop the mandatory national health insurance system

- Ensure control over the drug procurement and transparent administration:

  — Consider introduction of the obligatory publication of the information on drug availability by hospitals;

- Develop the hospital drug formulary system:

  — Ensure alignment of the hospital drug formularies with the National Guidelines and the clinical pathways being developed

- Introduce regulations for interchangeability:

  — Introduce clear rules on forming the state procurement orders for drugs (e.g. by INN);

  — Introduce the list of drugs that are to be not considered interchangeable including biological products and drugs with the narrow therapeutic index

5. Enforce proper protection of intellectual property rights:

- Extend regulatory data protection periods for biological and orphan drugs, as well as for new indications which require additional clinical studies;

- Make information on the drugs under registration process publicly available to ensure transparency of the regulatory data protection mechanism;

- Embed the data exclusivity and patent protection status review into the generic drug registration process to prevent marketing of products that violate intellectual property rights;

- Develop the system of preliminary injunctions against patent infringements;

— Specify grounds for compulsory licensing: develop a set of clear criteria under which the government may apply the compulsory licensing mechanism in line with WTO conditions for issuing the compulsory licensing under the TRIPS agreement;

— Enforce the trademark protection: develop a mechanism to prevent illegal use of confusable drug trade names similar to those of original drugs by generic drug companies

Conclusion

The recommendations developed within this project offer a pathway to a globally-competitive innovative pharmaceutical industry in Ukraine, improvement of the health of the Ukrainian citizens and increase in the welfare of the country.

By following the steps that project researchers have suggested, Ukraine can readily accomplish the major goals set by the Ukrainian government:

- Ukrainian citizens will have greater access to modern and effective medicine of the highest quality, getting the benefits that will come with improvement in healthcare;
- The Ukrainian pharmaceutical industry will become more attractive for investors who will fuel Ukraine's growth as a leader in pharmaceutical innovation.

2 ACKNOWLEDGEMENTS AND METHODOLOGY

Acknowledgments

The American Chamber of Commerce in Ukraine (The Chamber), Association of Pharmaceutical Research and Development (APRaD), PricewaterhouseCoopers Russia B.V. and PricewaterhouseCoopers LLC Ukraine B.V. (PwC) express our deep gratitude to all the representatives of the pharmaceutical industry in Ukraine who devoted their time and efforts to this project. This research would not have been possible without information provided by these industry experts.

We want to express our sincere appreciation to all the external experts — government officials and representatives of scientific community- who shared their opinion on the possibilities for the pharmaceutical market and healthcare system in Ukraine.

We especially thank policy-makers participating from the President's Administration, Verkhovna Rada, Ministry of Health, Ministry of Foreign Affairs, State Administration of Ukraine on Medicinal Products. Their extensive experience and unique insights allowed us to expand considerably the context of this project and increase its value.

Also we thank Professor Meir Pugatch and Pugatch Consilium Ltd Company, our partner in the development of a critical research tool for this report, the Biopharmaceutical Competitiveness Index (BCI) survey.

Methodology

For this report, the methodology consists of 5 different and complementary work streams

1. Pharmaceutical industry and healthcare system assessment

- Analysis of the pharmaceutical industry and healthcare system in Ukraine — current status, assets and trends;

2. Regulatory landscape analysis

- Biopharmaceutical Competitiveness Index survey (in cooperation with Pugatch Consilium Ltd.) to identify key areas for improvement in the Ukrainian healthcare and pharma regulation that affect innovation and investment;

3. Benchmark analysis

- International comparison of the position of Ukraine vs. international best practices to identify key areas for improvement in policies and regulation;
- Analysis of the international best practice examples in specific areas of regulation and identification of the rationale for improvement.

4. Strategic roadmap development

- Detailed recommendations and road maps to close gaps in areas for improvement and leverage best practice.

5. Stakeholder engagement

- Interviews and workshops with the government authorities, academia, pharmaceutical and healthcare experts.

3 GOALS OF THE DOCUMENT

Background

In its Healthcare 2020 document, the Ukrainian Government expressed an interest in developing a strong healthcare sector, with the goal of developing and implementing new technologies, optimizing the organization and financing mechanisms of health care and improving the quality of human resources and the level of professional training and strengthening public health.

Achievement of this goal requires significant financial resources that are beyond current budgets. However, it is still possible with the attraction of the FDI to pharmaceutical industry across the whole value chain. Based on international experience, creation of the favourable environment for investment is hardly possible without a close collaboration between the government authorities, academia and pharmaceutical business.

For this project, the Chamber and APRaD partnered to support the development of a policy road map to help guide Ukraine in its aspiration to develop a competitive pharmaceutical sector that promotes local research and development, attracts international investment, and values the innovation that Ukrainian and international pharmaceutical companies develop. The ultimate objective is to ensure better access of Ukrainian citizens to breakthrough drugs and innovative treatments to ensure longer and better quality life.

Objectives of the document

The twin objectives of the document are to provide a Vision for how Ukraine can develop a strong pharmaceutical sector through attraction of foreign direct investment and improve the health of population through patient access to efficient medications

Current State	Vision 2020
Generic-oriented Pharma Industry	**Pharma Industry with Attractive Investment Environment and Access to Breakthrough Drugs**
Uncompetitive Clinical Trials (CT) Environment Delays in the CT authorization and cumbersome regulatory procedures limit attractiveness of the country for CT conduct	**Attractive Conditions for CTs** CT regulation and tax environment is attractive for a investments in all stages of CT
Inefficient Drug Registration System Delays in the drug registration process and gaps in the regulation limit adoption of new molecules and investment attractiveness of the country	**Efficient and Transparent Drug Registration System** Fast track for approval of new molecules and fully harmonized regulation
Need to Increase Population Coverage by Medicines Insufficient options of healthcare financing and access to new drugs.	**Balanced and Sufficiently Financed Reimbursement System** Reimbursement system values biopharmaceutical innovation and covers significant proportion of the Ukrainian population
Restrained Market Access for Innovative Health Technologies Current IP rights regulation and CME system limit the opportunity to launch and market new molecules effectively	**Efficient and Transparent Market Access for New Health Technologies** Regulation guarantees IP rights safeguard during the launch and marketing of new drugs and ensure the knowledge on their use is disseminated fast among HCPs

4 ROLE OF THE PHARMACEUTICAL INDUSTRY IN THE HEALTHCARE SYSTEM AND ECONOMY OF THE COUNTRY

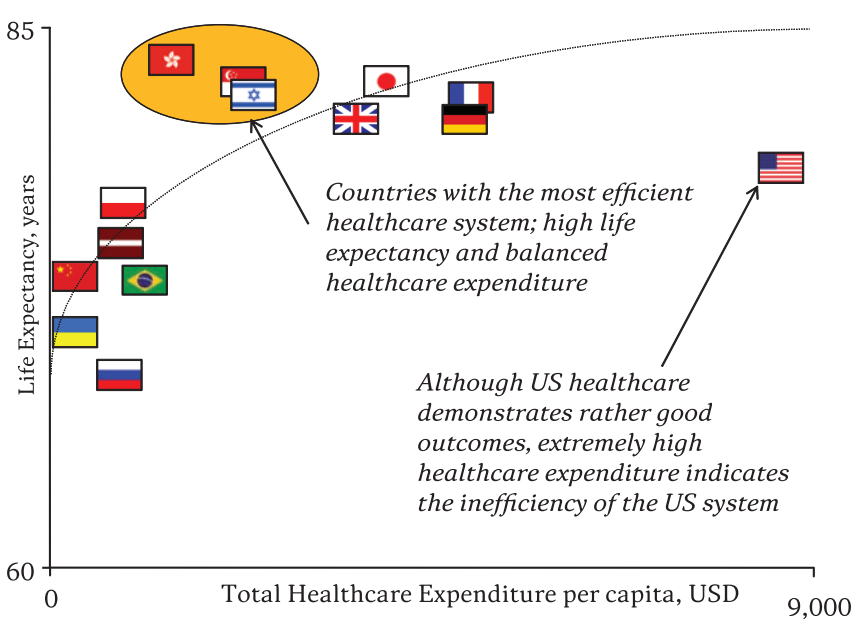
Role of the healthcare system in improvement of nation's health and development of economy

"Based on the first approximation, the economic value of increases in longevity over the twentieth century is about as large as the value of measured growth in non-health goods and services". The Health of Nations: The Contribution of Improved Health to Living Standards. William D. Nordhaus 2002.

Development of the healthcare system has a direct impact on the key life indicators in any country. As can be seen from the chart below a strong positive correlation between the amount of the health expenditure and life expectancy exist. At the same time, different countries demonstrate different levels of the healthcare system's efficiency with Hong Kong, Singapore and Japan being the leaders in this direction with the highest level of life expectancy in the world and the level of the health expenditure significantly below peers.

Efficiency of the health systems Impact of the health expenditure on life expectancy, 2011

Country	Rank among 51 countries*
Hong Kong	1
Singapore	2
Japan	3
Israel	4
UK	15
France	19
Poland	22
Latvia	23
Germany	33
China	38
US	47
Ukraine	49
Russia	50
Brazil	51

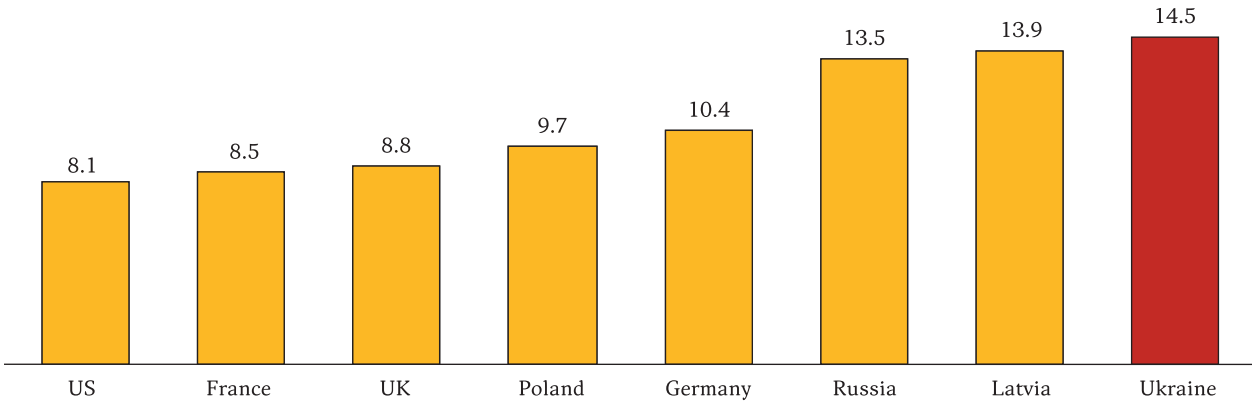


Source: *Bloomberg; World Bank; PwC analysis*

Note: **Bloomberg Index — each country was ranked based on three criteria: life expectancy (weighted 60%), relative per capita cost of health care (30%), and absolute per capita cost of health care (10%).*

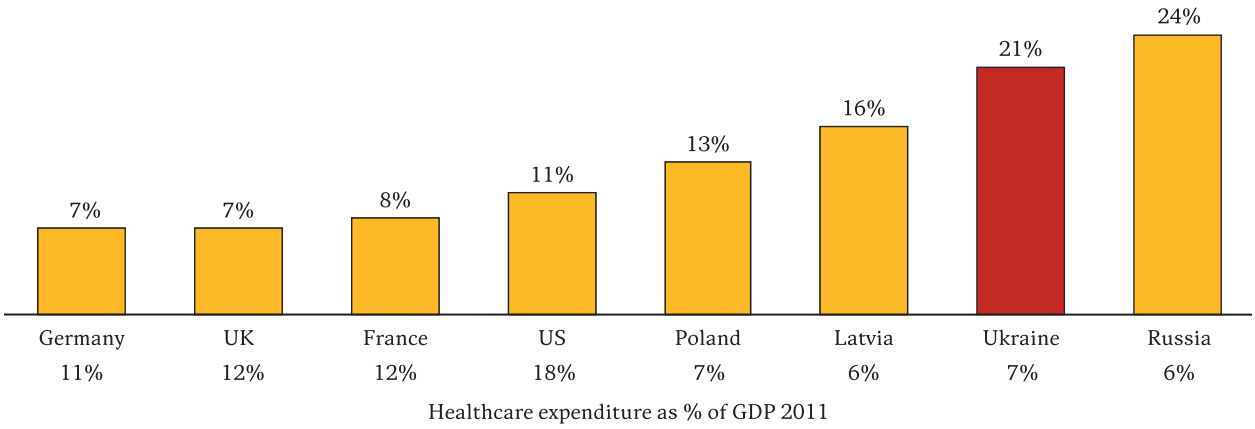
Development of the healthcare system and increase in healthcare spending also play a critical role in reduction of mortality rate. Although, the overall mortality rate is influenced significantly by the age structure of population, improvement in the healthcare system reduces significantly the premature mortality, which in turn has an impact on the economic growth through increase of the workforce and improvement of the productivity.

Mortality rate, number of deaths per 1 K of population, 2011



Source: *World Bank*

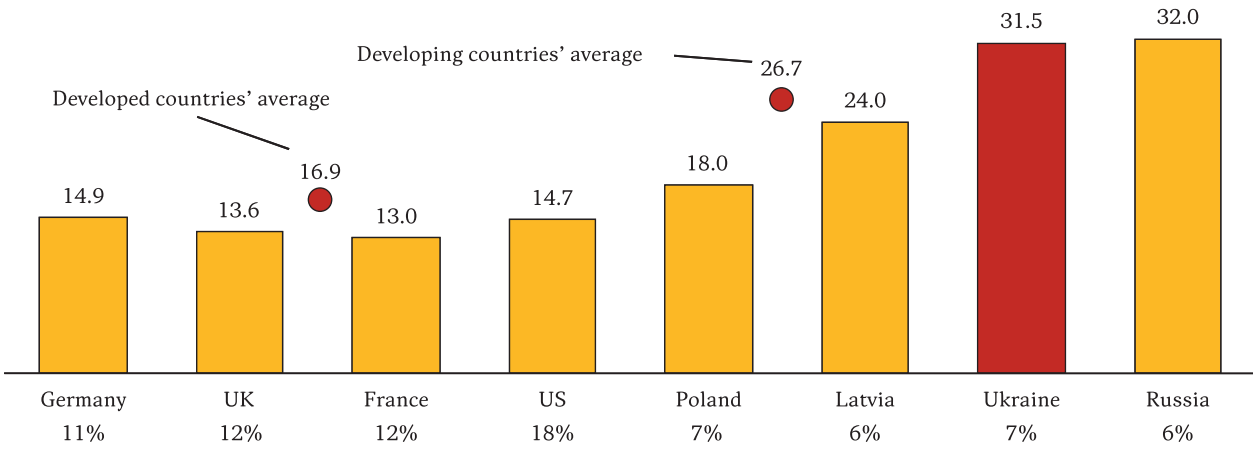
Adult mortality rate (probability of dying between 15 and 60 years)



Source: *WHO*

High level of the premature mortality (mortality of people of the working age) results in significant losses of the potential future GDP of the country, which could be produced by the people dying in the working age. The impact of the premature mortality on the economy can be assessed through the number of years of potential life lost, which indicates the total number of years that people in the country would have lived if they did not die prematurely.

Number of years of potential life lost (YLL) due to premature mortality, 2010, 1 K years per 100 K of population

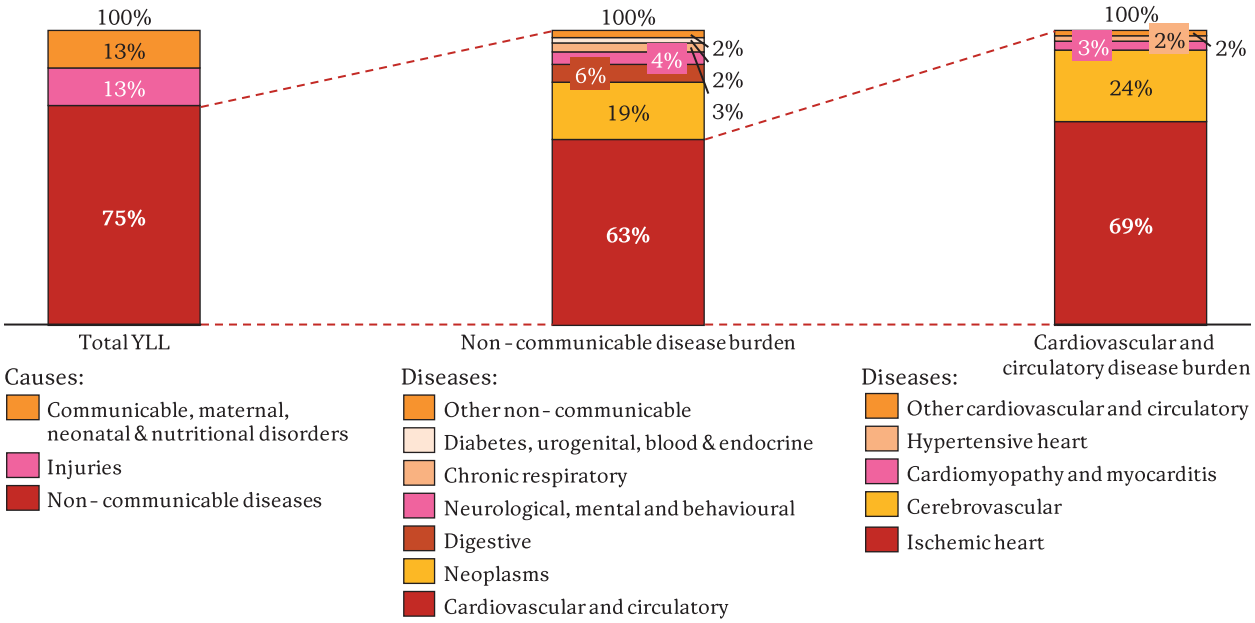


Source: *Global Burden of Disease Study 2013, Institute for Health Metrics and Evaluation*

Based on the 2010 levels of the GDP per capita and the number of years of potential life lost, only in 2010 Ukraine could have saved USD 6.6 B of the potential future GDP if the premature mortality was reduced to the average level of the developing countries, or USD 16.9 B in case the indicator was down to the average level of the developed countries.

Among the causes of the premature mortality in Ukraine the cardiovascular diseases account for 47.5% of the total number of deaths, while neoplasms account for another 14.3%. Thus, these two groups of disease account for approximately 62% of the economic losses associated with the premature mortality in Ukraine. Improvement in prevention, diagnosis and treatment of these groups of the diseases could bring significant contribution to both health and economy of Ukraine.

Structure of the number of years of potential life lost in Ukraine by the cause of death, 2010, %

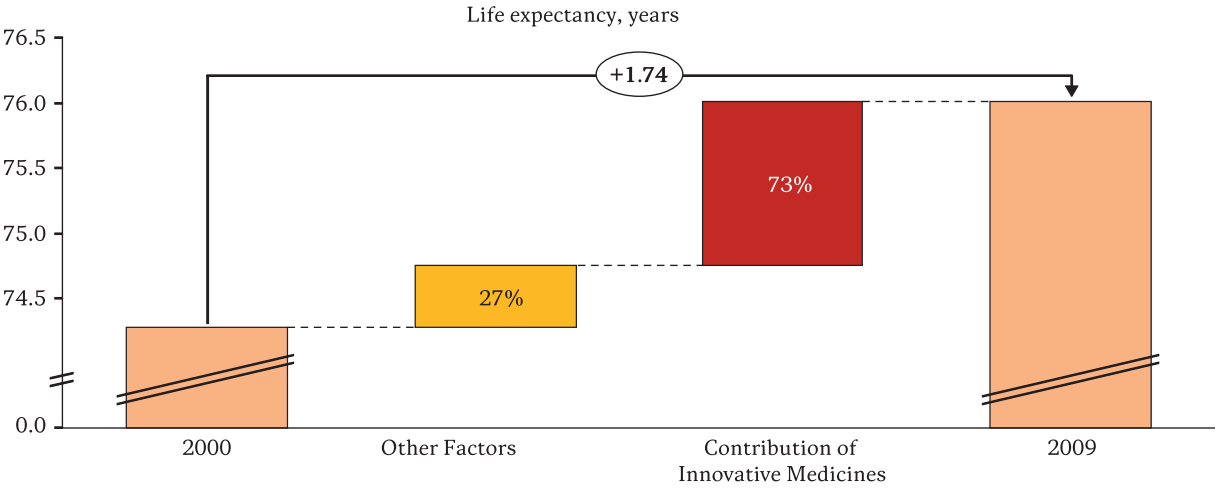


Source: *Global Burden of Disease Study 2013, Institute for Health Metrics and Evaluation*

The impact of pharmaceutical innovation on health

Among other segments of the healthcare system innovative pharmaceuticals play a critical role in the improvement of the health of population and key life indicators. If we consider international practice, we can clearly see that innovative drugs were the most significant contributor to the increase in the life expectancy, i.e. accounting for 73% of the improvement in 30 OECD countries in 2000–2009.

Life expectancy increase in 30 OECD Countries, 2000–2009



Source: *Lichtenberg F.: Pharmaceutical innovation and longevity growth in 30 developing OECD and high-income countries, 2000–2009*

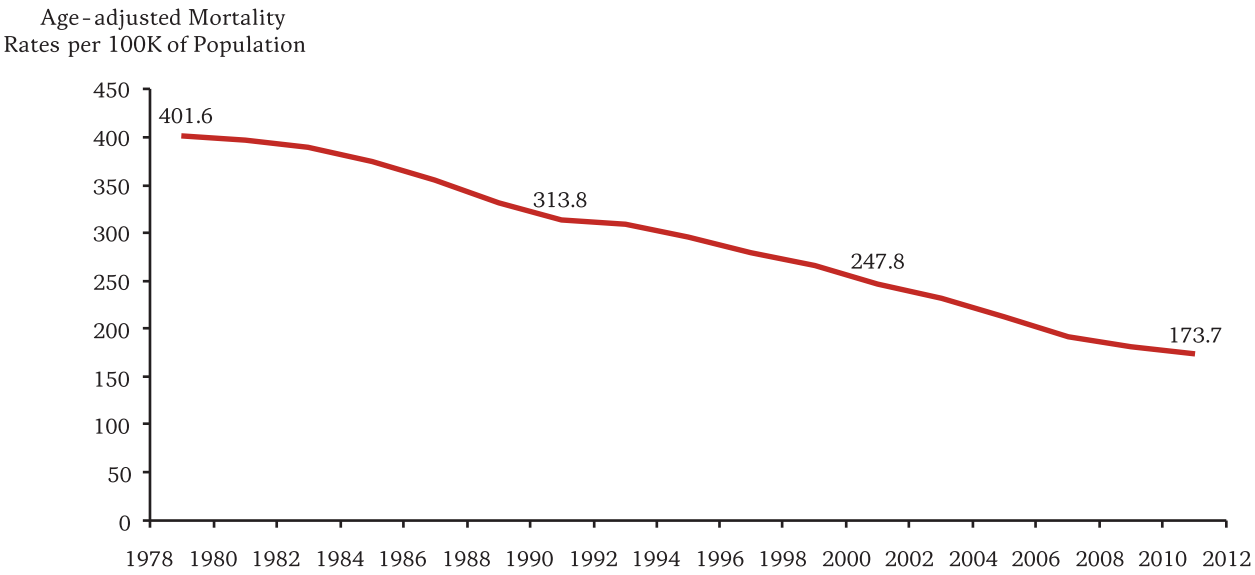
Pharmaceuticals play a critical role in treatment of the certain diseases critical for Ukraine, such as cardiovascular diseases, cancer and HIV/AIDS, which can be seen from the examples of US below.

Annual Hospitalizations and Deaths Avoided through Use of Recommended Antihypertensive Medications

	Annual Hospitalizations Avoided	Annual Premature Deaths Avoided
Prevention Achieved: Based on Current Treatment Rates	833,000	420,000
Potential Additional Prevention: If Untreated Patients Received Recommended Medicines	86,000	89,000

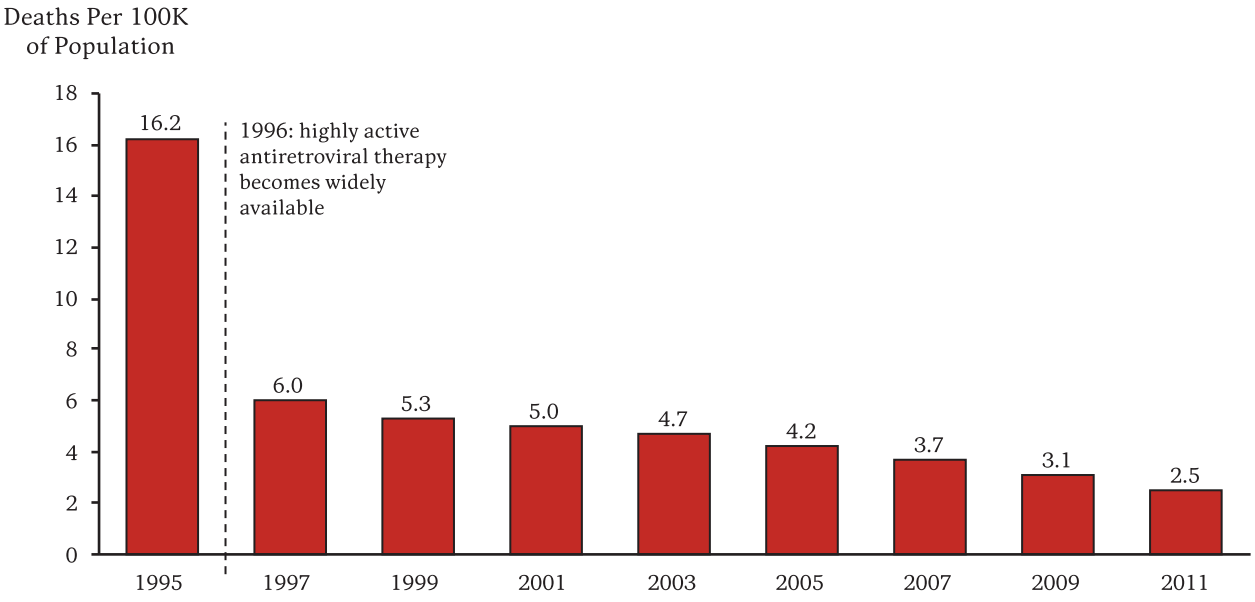
Source: *Cutler DM et al (2007) The value of hypertensive drugs: A perspective on medical innovation*

US mortality rate due to cardiovascular diseases, 1979–2011



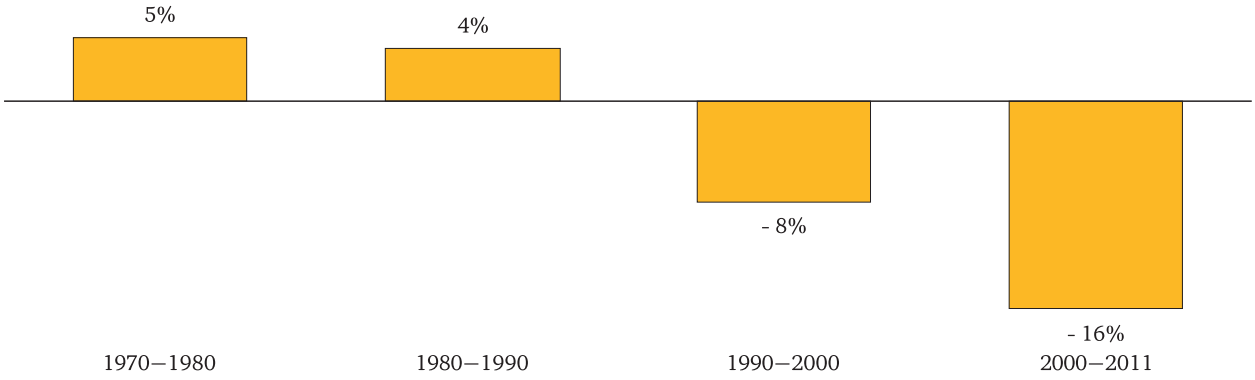
Source: *US Centre for Disease Control and Prevention*

Annual number of AIDS deaths in the US, 1995–2011



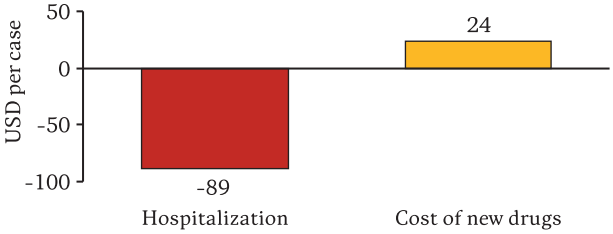
Source: *US Centre for Disease Control and Prevention*

Percent change by decade in the US mortality rates from cancer



Source: *US Centre for Disease Control and Prevention*

In addition, access to the modern medication leads to reduction of healthcare costs through prevention of the avoidable hospitalizations, which is illustrated by the international example below.



Cost of newer cardiovascular drugs compared to savings in hospitalization in 20 OECD countries, 1995–2003

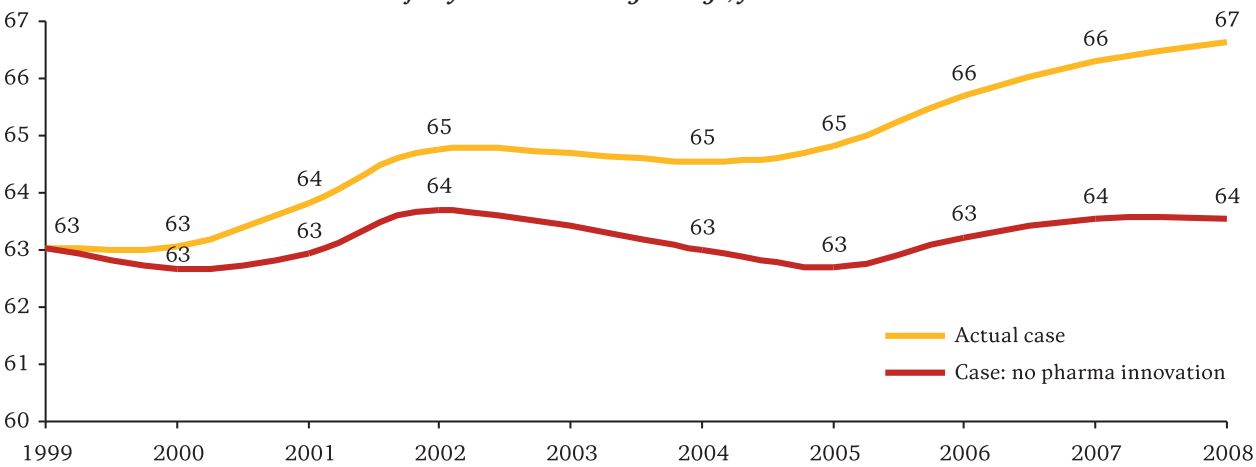
Source: *Lichtenberg FR (2009) Have newer cardiovascular drugs reduced hospitalization? Evidence from longitudinal country-level data on 20 OECD countries, 1995–2003.*

Pharmaceuticals were not the only reason for the improvement in the health outcomes: better medical equipment, improvements in diagnostics, increased number of the HCPs supply and educational campaigns for patients — all these reasons contributed to the current improvements in healthcare. However, as it was mentioned above, the impact of the pharmaceuticals accounts for 73% of the overall improvement.

What would be the outcome without innovative medicines? The research made by professor Lichtenberg in Turkey indicates that from 1999 to 2008, mean age at death in Turkey increased by 3.6 years, from 63.0 to 66.6 years. In the absence of any pharmaceutical innovation, mean age at death would have increased by only 0.6 years. Hence, pharmaceutical innovation was estimated to have increased mean age at death in Turkey by 3.0 years during the period 1999–2008.

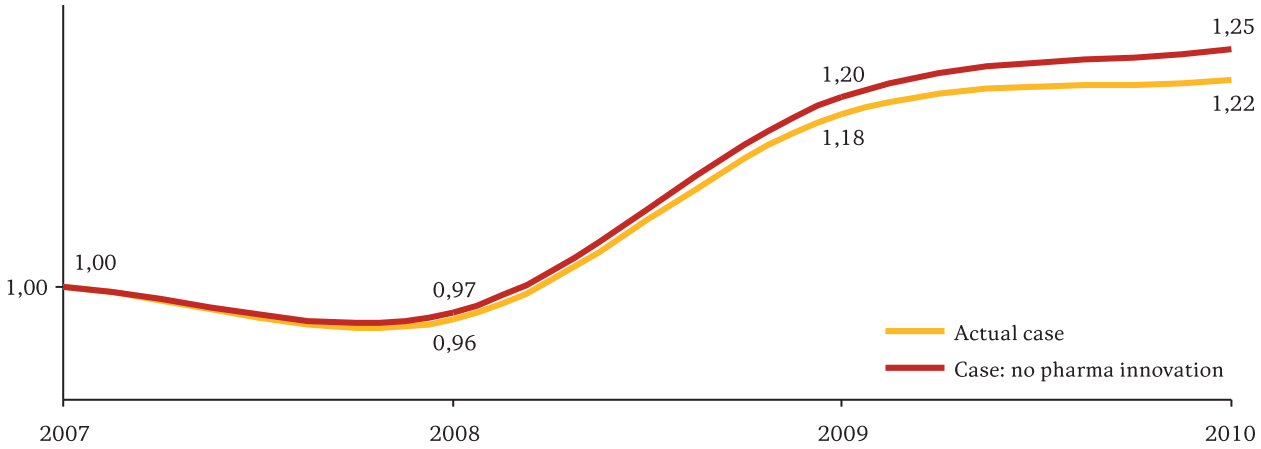
The estimates of the effect of pharmaceutical innovation on hospital utilization indicated that an increase in the number of molecules used to treat a disease reduces the number of hospital days due to the disease 3–4 years later. It was estimated that pharmaceutical innovation has reduced the number of hospital days by approximately 1% per year.

Comparison of the actual increase in mean age at death to the increase that would have occurred in the absence of any increase in drug vintage, years



Source: *Lichtenberg, The effects of pharmaceutical innovation on mortality, hospitalization and medical expenditures in Turkey, 1999–2010*

Hospital days, 2007–2010: Actual vs. in the absence of pharmaceutical innovation



Source: *Lichtenberg, The effects of pharmaceutical innovation on mortality, hospitalization and medical expenditures in Turkey, 1999–2010*

The estimates of the effect of pharmaceutical innovation on age at death, hospital utilization and pharmaceutical expenditure to assess the incremental cost-effectiveness of pharmaceutical innovation, i.e., the cost per life-year gained from the introduction of new drugs shows that the cost per life-year gained from pharmaceutical innovation is $2,813. The results indicate that innovative drugs are highly cost effective options for the Turkish health care system. Apart from their invaluable contribution to longevity, this contribution is also value for money.

Estimation of Incremental Cost-effectiveness of Pharmaceutical Innovation in Turkey, 1999–2008

	Life expectancy (mean age at death)	Annual per capita health expend (USD)	Lifetime per capita health expend (USD)	ICER (USD)
Actual value in 2008	67.1	906	60,798	2,813
Estimated value in 2008 in the absence of the 9 previous years of pharmaceutical innovation	64.1	818	52,471	
Difference	3.0	88	8,327	

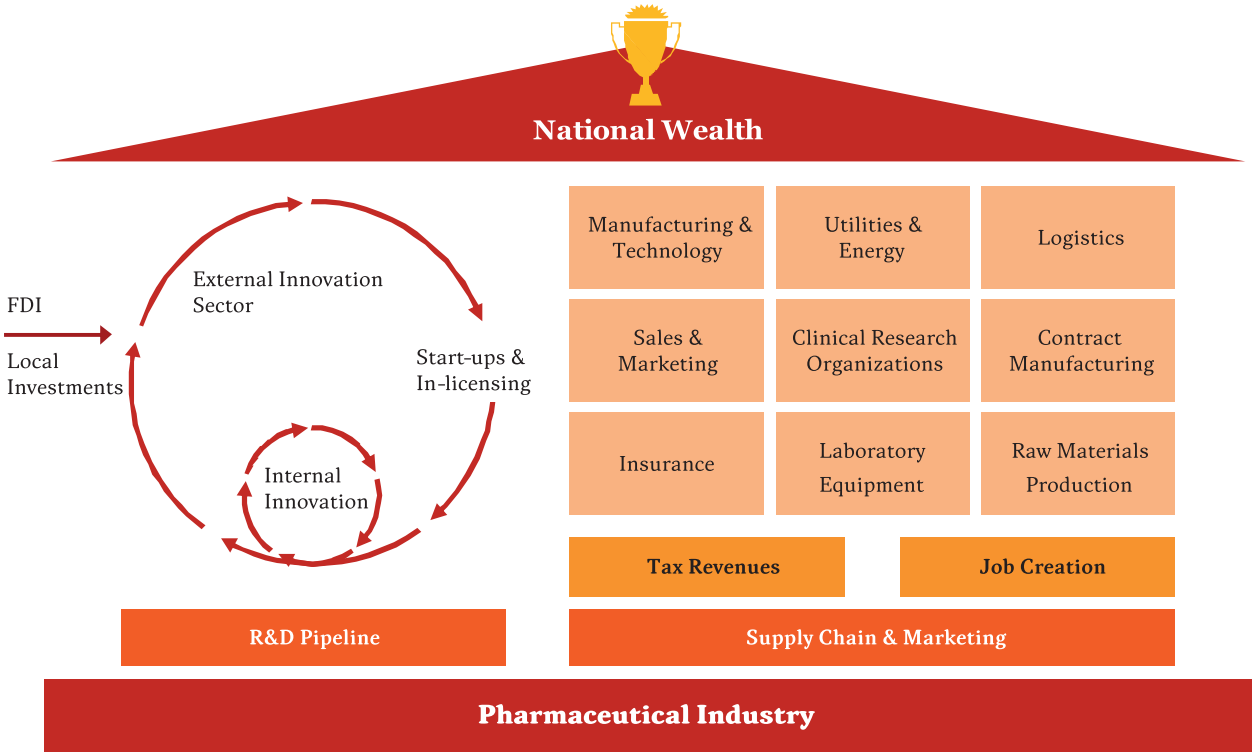
Source: *Lichtenberg, The effects of pharmaceutical innovation on mortality, hospitalization and medical expenditures in Turkey, 1999–2010*

As additional example, if the fraction of drugs consumed that were less than 20 years old increased from its actual value in Russia (1%) to the mean value of all 31 countries (9%), life expectancy at birth in Russia would increase by about 2.1 years (Lichtenberg 2013, The potential contribution of increased new drug use to Russian longevity and health).

The impact of the innovative pharmaceutical industry on the economy

There is no doubt that innovative pharmaceuticals increase life expectancy. But the real impact is much broader — innovative drugs lead to a country's prosperity. The positive impact consists of: increase in productivity and workforce, business operations and job creation, education of physicians and patients, transfer of know-how, the general increase of the level of medical knowledge in the country, inflow of additional tax revenues, etc.

The Biopharmaceutical Sector — The Foundation of a Business Ecosystem



As a practical example, the US pharmaceutical sector generated nearly $54,8B in federal tax revenues in 2012; it also triggered 4M jobs in other industries. The overall economic contribution of the U.S. innovative pharmaceutical sector is multidimensional, with the positive influence on:

- Personal income: Cash, benefits and non-cash payments received by individuals in the economy;
- Value-added production: The difference between an industry's or an establishments total output and the cost of its intermediate inputs;
- Output: The dollar value of production (i.e. sales);
- Direct impact: The specific impact of biopharmaceutical sector expenditures in the first round of spending;
- Indirect impacts: The impact of expenditures by suppliers to the biopharmaceutical sector;
- Induced impacts: The additional economic impact of the spending of biopharmaceutical sector employees and suppliers' employees in the overall economy that can be attributed to direct biopharmaceutical industry expenditures.

Economic Impacts of the U.S. Biopharmaceutical Sector, 2009 ($B)

	Employment	Personal Income	Value Added	Output	State/ Local Tax Revenue	Federal Tax Revenue
Direct Effect	674 192	80	131	382	4	15
Indirect Impacts	1 403 511	92	142	262	12	19
Induced Impacts	1 935 738	86	153	274	16	19
Total Impact	4 013 441	258	426	918	33	53

Source: *Battelle Technology Partnership Practice*

There are more than 0.6M jobs in the US biopharmaceutical sector and each biopharmaceutical job supports 5 additional jobs in other sectors: 4M total US jobs supported by the biopharmaceutical sector.

Case studies of success in development of the innovative pharmaceutical industry

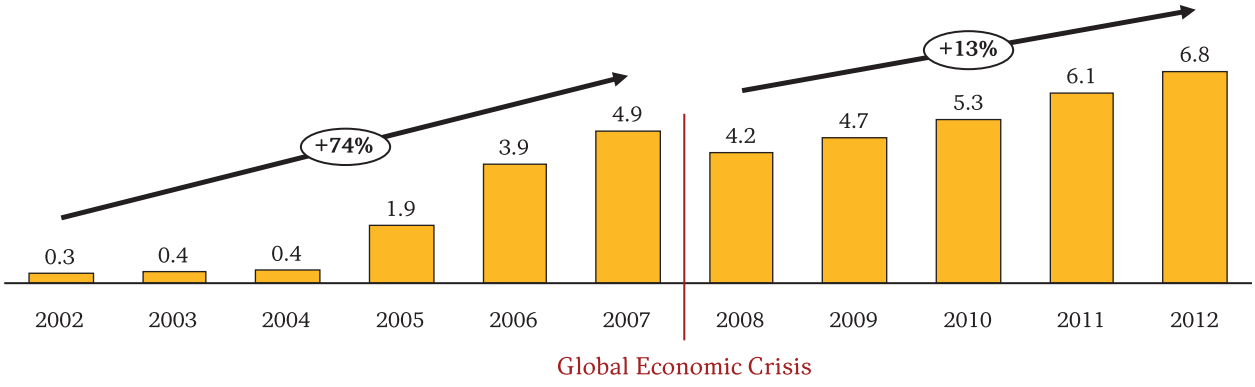
Examples of other countries demonstrate how transparent, consistent and comprehensive government policy can support the rapid development of the biopharmaceutical sector providing incentives for the international pharmaceutical companies to invest in the production and R&D in a country. Development of the biopharmaceutical sector in such countries brings significant benefits both in terms of healthcare and economic growth. Singapore and Ireland demonstrate the most impressive results in this respect with the innovative pharmaceutical industry built from scratch in the last decades.

Development of the innovative pharmaceutical industry in Singapore

Singaporean pharmaceutical industry has over 30-year history dating back to 1979 when GlaxoSmithKline set up operations in the country and establishment of the Singapore Science Park in 1980 providing an infrastructure for R&D. During 1990s the industry development was characterized by attraction of foreign investment in manufacturing with international pharmaceutical companies such as MSD and Sanofi setting up production in Singapore. Finally, in 2000s pharmaceutical R&D became the focus of the industry development which supported further rapid development of the biopharmaceutical sector in Singapore.

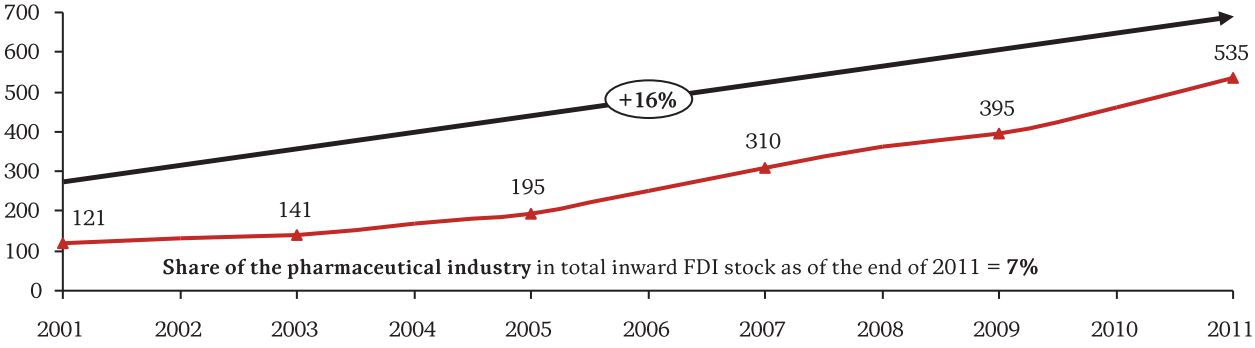
Development of the innovative pharmaceutical industry brought significant economic benefits to Singapore with the export of pharmaceutical products demonstrating over 20-fold growth in 10 years from 2002 to 2012 and pharmaceutical industry contributing 7% to the total inward FDI volume in 2011. Rapid development of the pharmaceutical industry contributed to fast growth of Singaporean economy with GDP increased by more than 40% in real terms in 10 years from 2002 to 2012.

Export of pharmaceutical products from Singapore, USD B, 2002–2012



Source: *BMI; International Trade Centre*

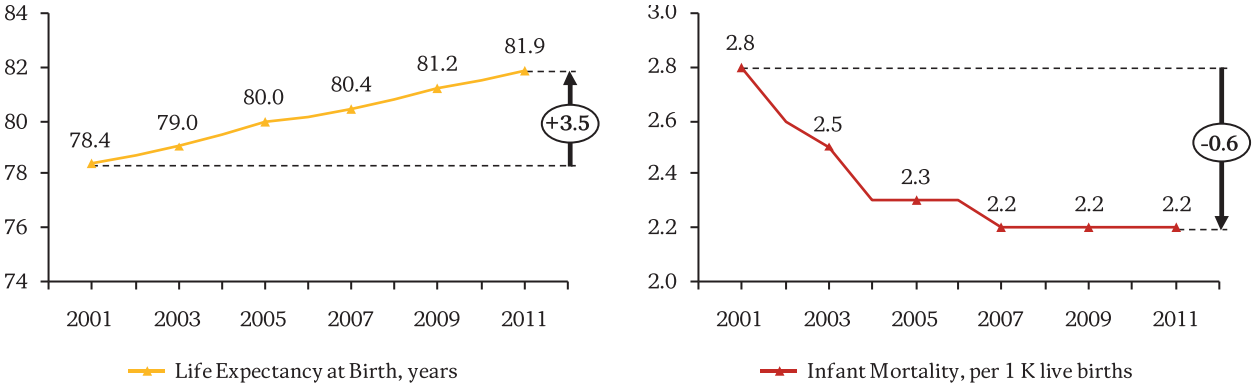
Total inward FDI stock as at year end in Singapore, USD B, 2001–2011



Source: *Department of Statistics Singapore*

Besides the obvious economic effect, development of the pharmaceutical industry in Singapore led to a better medicines availability, and significant progress in disease treatment which contributed to a fast improvement of the vital statistics in Singapore in 2001–2011.

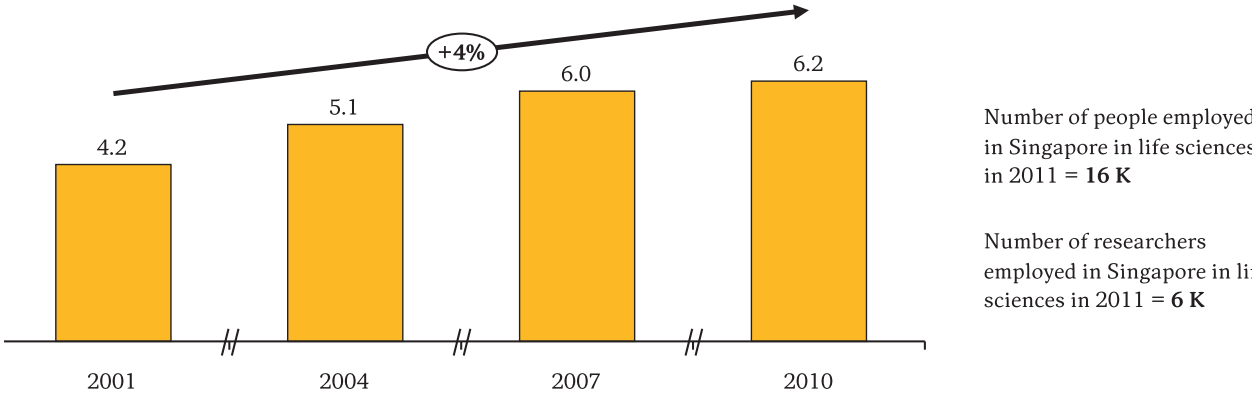
Life indicators in Singapore, 2001–2011



Source: *World Bank*

In addition to the healthcare and economic impact development of the innovative pharmaceutical industry resulted in creation of the skilled jobs with the number of researchers per 1 K of people in Singapore increased from 4.2 to 6.2 in 2000–2010 and the total number of people employed in life sciences in Singapore reached 16 K in 2011.

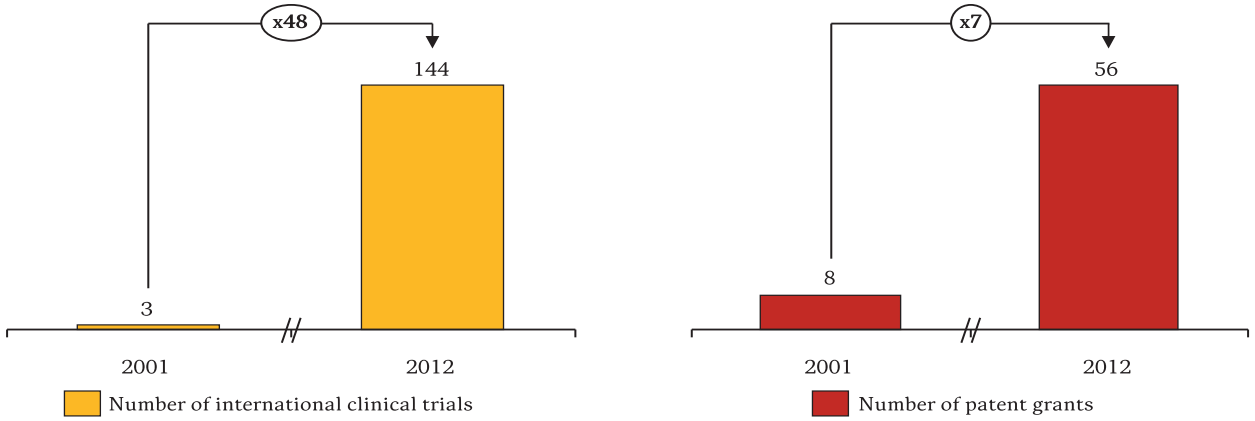
Number of researchers in R&D in Singapore, per 1 K of people, 2000–2010



Source: *World Bank*

The progress of the pharmaceutical R&D in Singapore in 2000s is characterized by the rapid increase in the number of international clinical trials initiated in Singapore and the number of patents granted to Singaporean scientists in the field of pharmaceuticals.

The number of international interventional clinical trials initiated and the number of patent grants in pharmaceuticals, Singapore, 2001–2012



Source: *clinicaltrials.gov, World Intellectual Property Organization*

The rapid development of the innovative pharmaceutical industry in Singapore was a result of the active government support and attractive policy environment across the whole value chain of the pharmaceutical industry from drug discovery to market access. The summary of the relevant policies and government initiatives in Singapore at different stages of the pharmaceutical value chain is provided below.

1. **Drug discovery**

- Government financing Programs to support research such as R&D grants provided by the Agency for Science and Technology
- Extensive tax incentives for R&D including 400% tax deduction for R&D expenses
- Government support of the talent pool development including scholarship Programs and open immigration policy
- Development of the R&D infrastructure such as Biopolis technology park
- Strong, coherent and well-enforced patent laws
- Communication and partnership between the government and international pharmaceutical companies

2. **Clinical trial environment**

- Harmonization of the clinical trial regulation with internationally recognized rules of GCP (Good Clinical Practice)
- Fast process of review and approval of clinical trial applications (30 days)
- Expanding clinical research capabilities in healthcare services through government Programs and grants
- Tax incentives for conduct of clinical trials
- Providing guidance to companies on the clinical trials regulation

3. **Manufacturing**

- Creation of a favourable environment for investment in manufacturing, including:
  - — Attractive tax regime (low corporate tax and tax incentives)
  - — Favourable foreign direct investment regulation (i.e. equal regulation for local and foreign investors, no foreign ownership restrictions, highly liberal foreign exchange regime, etc.)
- Development of the physical infrastructure able to support advanced manufacturing

4. **Regulatory system**

- Harmonization of the requirements to the drug market authorization with the recommendations of the International Conference on Harmonization
- Provision of the fast track for approval of new drugs (As short as 60 or 180 in case the drug was registered in 1—2 of the basket countries, 270 days in case of an absolutely new drug to be registered fır the first time in the world)

5. **Market access**

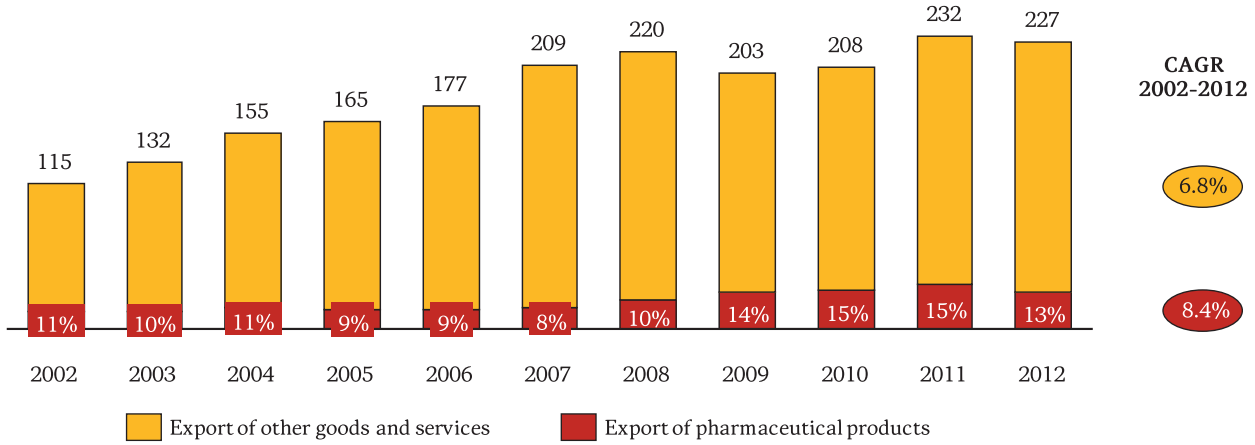
- Extensive network of free trade agreements in Asia providing access to large and fast growing pharmaceutical markets
- Strong, comprehensive and well-enforced intellectual property rights regime, including:
  - — Strong patent protection including patent linkages (i.e. a generic drug cannot get market authorization until the expiry of a patent of a reference product) and court specialization
  - — Regulatory data protection in line with the WTO requirements

Development of the innovative pharmaceutical industry in Ireland

The start of development of the Irish biopharmaceutical industry dates back to 1960's however the rapid development of the sector began in 1990's with the initiation of the government "Biotechnology Strategy", strong focus on the attraction of FDI to the industry and government support of the pharmaceutical research commercialization. The rapid development of the Irish biopharmaceutical industry continued in 2000's with the prioritization of the biotechnology sector in the National Development Plans in 2000—2006 and 2007—2013 and strong government support of pharmaceutical R&D.

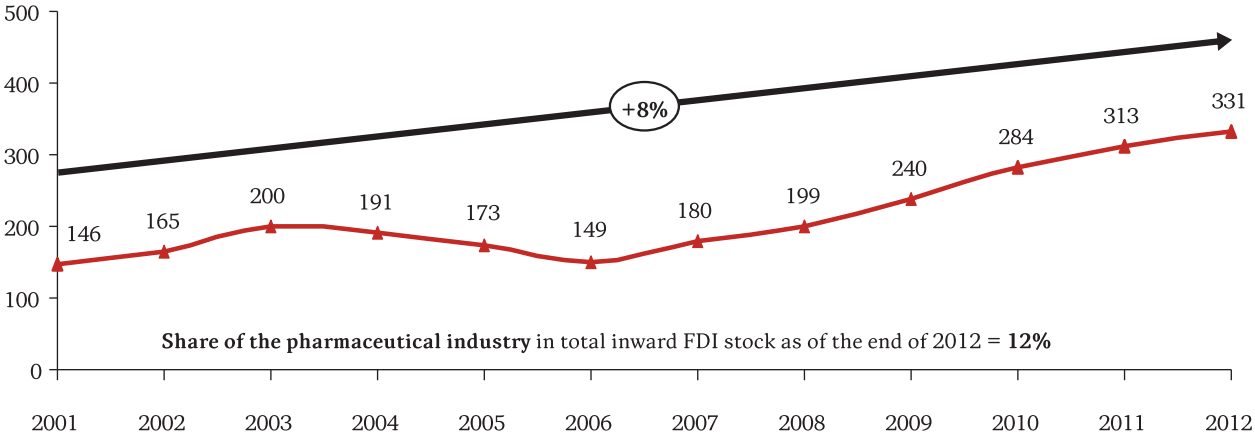
With the development of the pharmaceutical R&D and manufacturing pharmaceutical industry became one of the most important segments of the Irish economy with the export of pharmaceutical products from Ireland growing by 8% per annum on average in 2002—2012 and accounting for 12% of the total export of goods and services from Ireland in 2012. Pharmaceutical sector also contributed significantly to the rapid growth of the amount of FDI attracted by the Irish economy. Pharmaceutical industry accounted for 12% of the total inward FDI stock in Ireland as of the end of 2012.

Export of goods and services from Ireland, USD B, 2002–2012



Source: *BMI; International Trade Centre; World Bank*

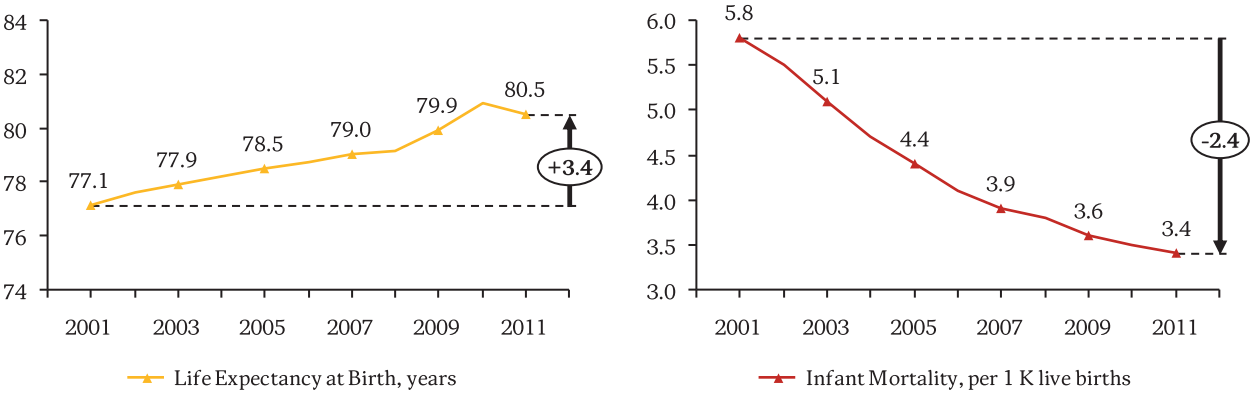
Total inward FDI stock as at year end in Ireland, USD B, 2001–2012



Source: *Central Statistics Office of Ireland*

Similar to the case of Singapore, development of the innovative pharmaceutical industry in Ireland also contributed to improvement of the vital statistics.

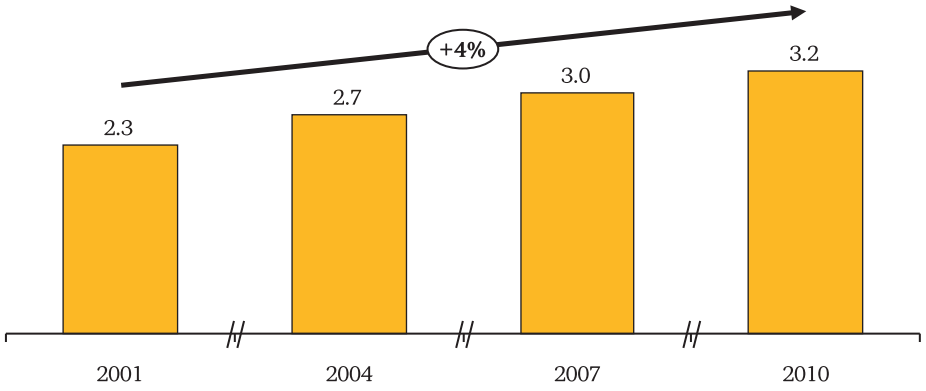
Life indicators in Ireland, 2001–2011



Source: *World Bank*

The pharmaceutical sector employed 23 K people in Ireland in 2010 and contributed to 50% increase in number of researchers per 1K of population in 2000–2010 in the country.

Number of researchers in R&D in Ireland, per 1 K of people, 2000–2010

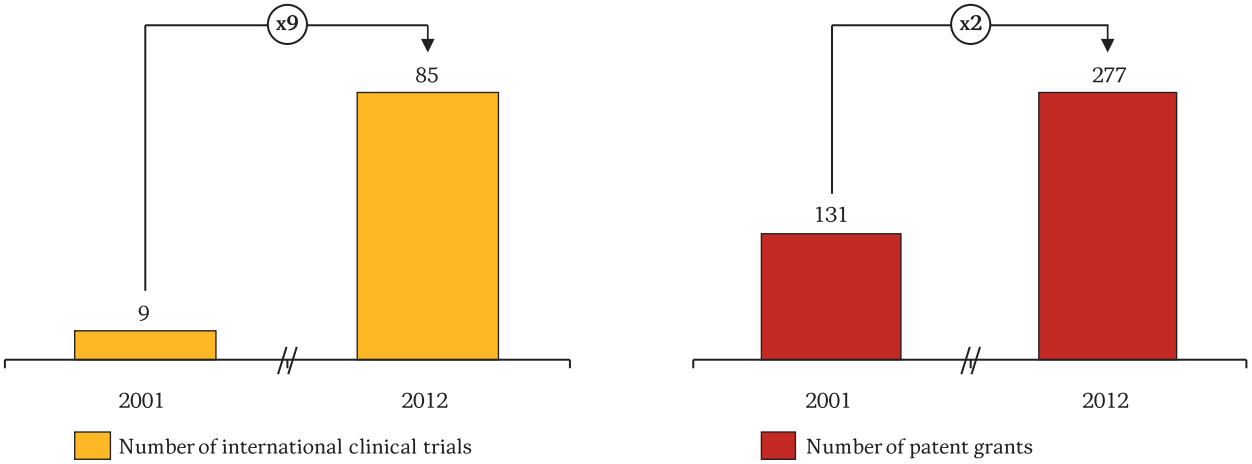


Number of people employed in pharmaceutical industry in Ireland in 2011 = **24K**

Source: *World Bank*

The number of the patents in pharmaceuticals granted to the Irish scientists increased twice in 2001–2012 and the number of the international interventional clinical trials initiated in Ireland in 2012 was 9 times higher than in 2001 demonstrating the rapid progress in the pharmaceutical R&D.

The number of international interventional clinical trials initiated and the number of patent grants in pharmaceuticals, Ireland, 2001–2012



Source: *clinicaltrials.gov, World Intellectual Property Organization*

As in the case of Singapore, rapid development of the biopharmaceutical industry in Ireland was a result of comprehensive and consistent government policy and initiatives across the whole pharmaceutical industry value chain. The summary of the relevant policies and government initiatives in Ireland at different stages of the pharmaceutical value chain is provided below.

1. Drug discovery

- Significant government funding for biotechnology R&D provided by the state agencies such as Enterprise Ireland and the Industrial Development Authority
- R&D tax credit of up to 20% for any increase in R&D activity and no taxes on the earnings from the intellectual property rights objects created in Ireland
- Government support of the talent pool development including scholarship Programs and development of the graduate and postgraduate Programs in biotechnology in cooperation with the industry
- Development of the R&D infrastructure through a network of science parks
- Strong, coherent and well-enforced patent laws
- Communication and partnership between the government and international pharmaceutical companies supported by establishment of the dedicated agencies such as Pharma Chemical Ireland bringing together all relevant stakeholders

2. Clinical trial environment

- Establishment of the Irish Clinical Research Infrastructure Network dedicated to improve Ireland capacity to conduct clinical research

- Harmonization of the clinical research regulation with the internationally accepted best practices
- Constant dialogue between the government and the industry on the clinical trial regulation

3. Manufacturing

- Creation of a favourable environment for investment in manufacturing, including:

— Attractive tax regime (low corporate tax and tax incentives)

— Favourable foreign direct investment regulation (i.e. equal regulation for local and foreign investors, no foreign ownership restrictions and liberal visa / residency requirements)

4. Regulatory system

- Harmonization of the requirements to the drug market authorization with the recommendations of the International Conference on Harmonization
- Provision of the fast track for approval of new drugs

5. Market access

- Easy access to the large EU pharmaceutical market
- Strong, comprehensive and well-enforced intellectual property rights regime, including:

— Strong patent protection

— Regulatory data protection above the WTO requirements in line with the EU practice (8+2+1 years scheme)

- Free pricing control

5 COMPARISON OF THE UKRAINIAN HEALTHCARE AND PHARMACEUTICAL SECTOR TO INTERNATIONAL COUNTERPARTS

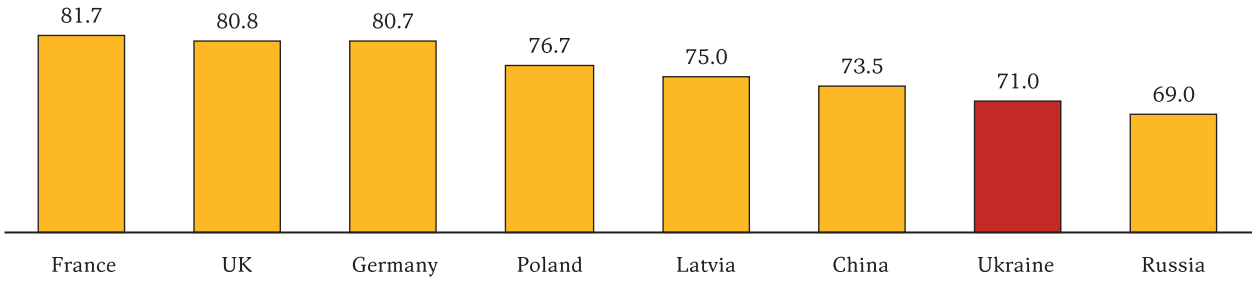
Comparison of the Ukrainian healthcare system to international counterparts

In order to assess the current healthcare system of Ukraine we compared the indicators characterizing its efficiency versus developed and developing countries across the key elements of the system, including:

- Overall health system performance
- Health system financing
- Human resources for health
- Service delivery
- Access to medicines

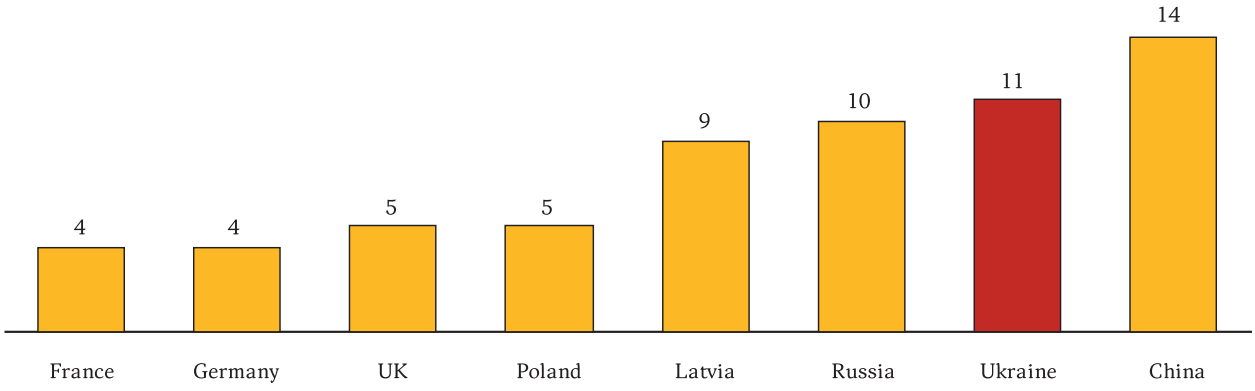
Overall health system performance

Life expectancy at birth, years, 2013



Source: *World Bank*

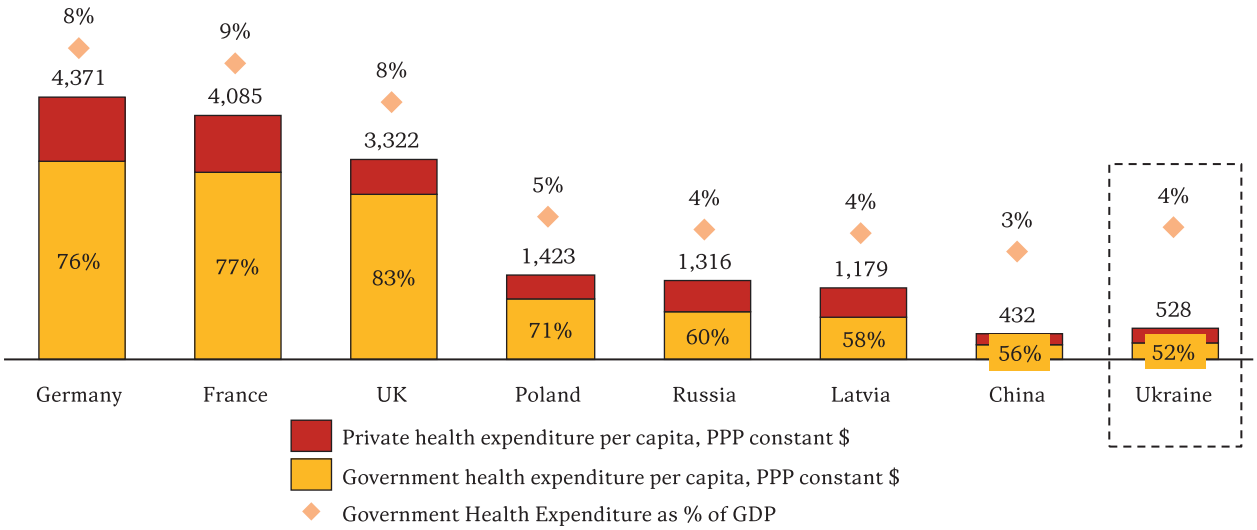
Mortality rate, under-5, per 1 K live births, 2011



While there was a significant progress in the life expectancy and improvement of the death rates during the last decade, Ukraine is still behind other developed countries, including CEE countries. Recent economic and consequent budget restraints put further pressure on the government financing

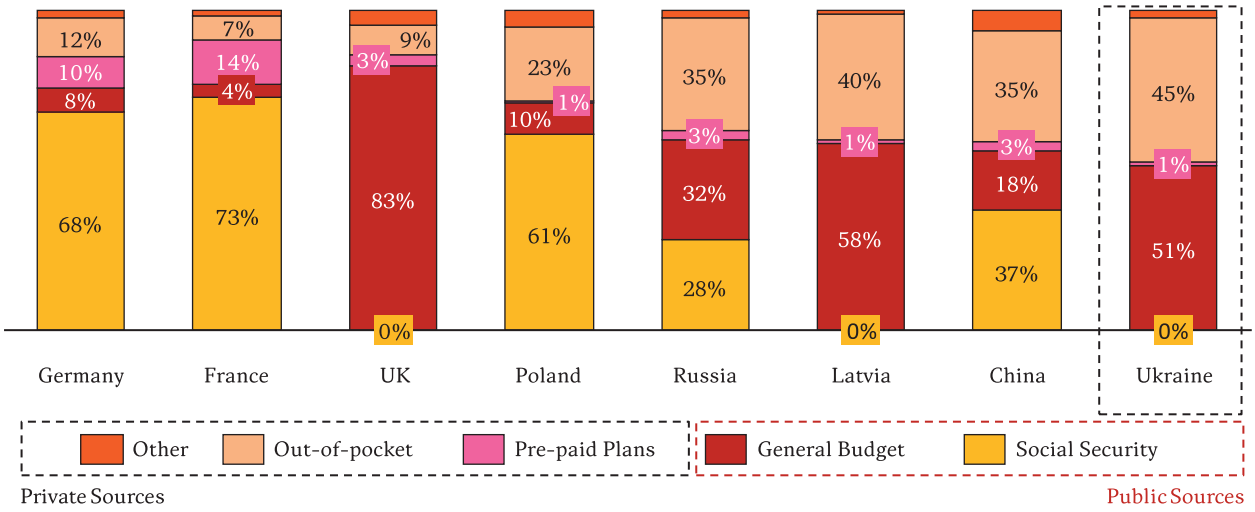
Health system financing

Total health expenditure 2011, USD ppp (constant 2005)



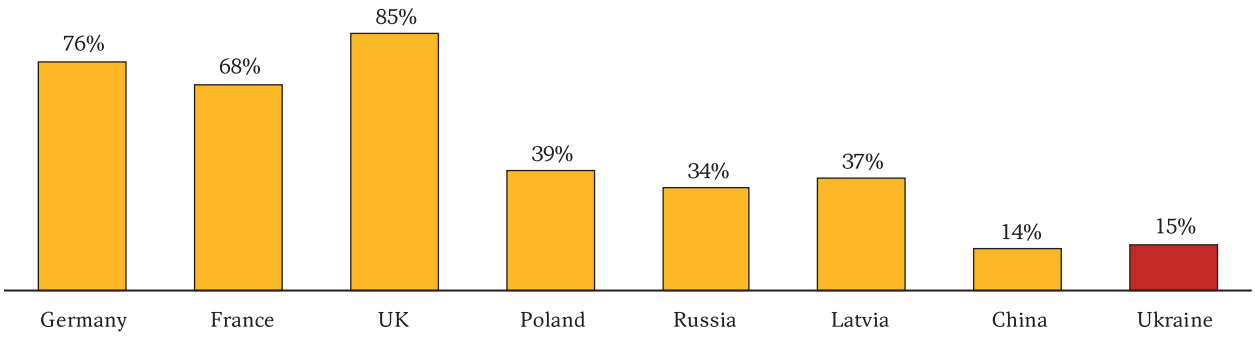
Source: *World Bank*

Health expenditure structure by source of financing 2011, %



Source: *WHO*

Share of government financing in total expenditure on pharmaceuticals (incl. hospital segment), 2011, %

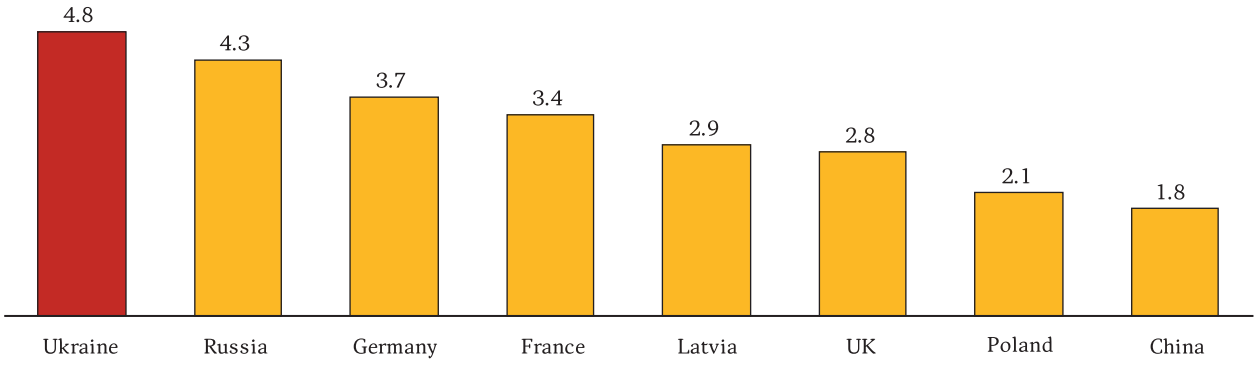


Source: *WHO*

Ukraine's public health care expenditure almost tripled from 1996 to 2011 in absolute terms but still health care expenditure in the GDP are far below other countries. Ukraine also does not have a developed healthcare insurance system, which significantly limits the level of healthcare financing.

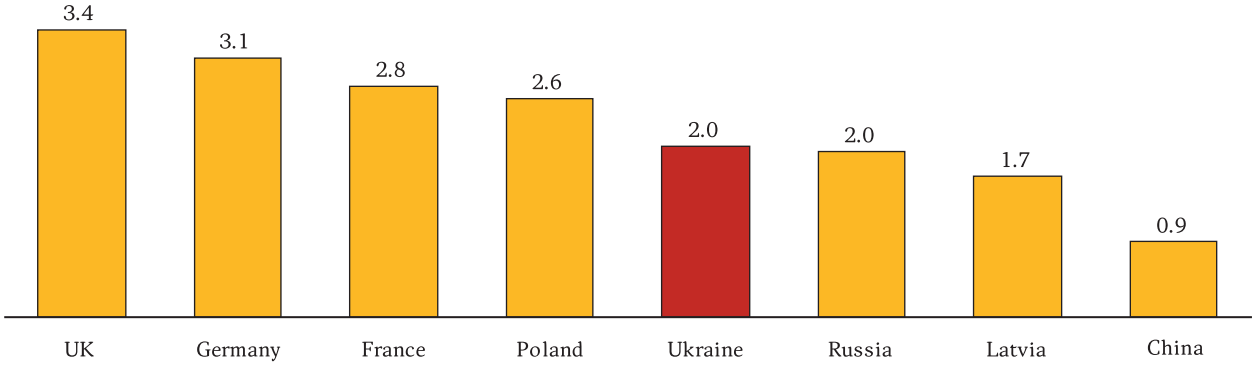
Human resources for health

Number of physicians per 1 K people, 2011



Source: *World Bank*

Number of nurses and midwives per 1 physician, 2011

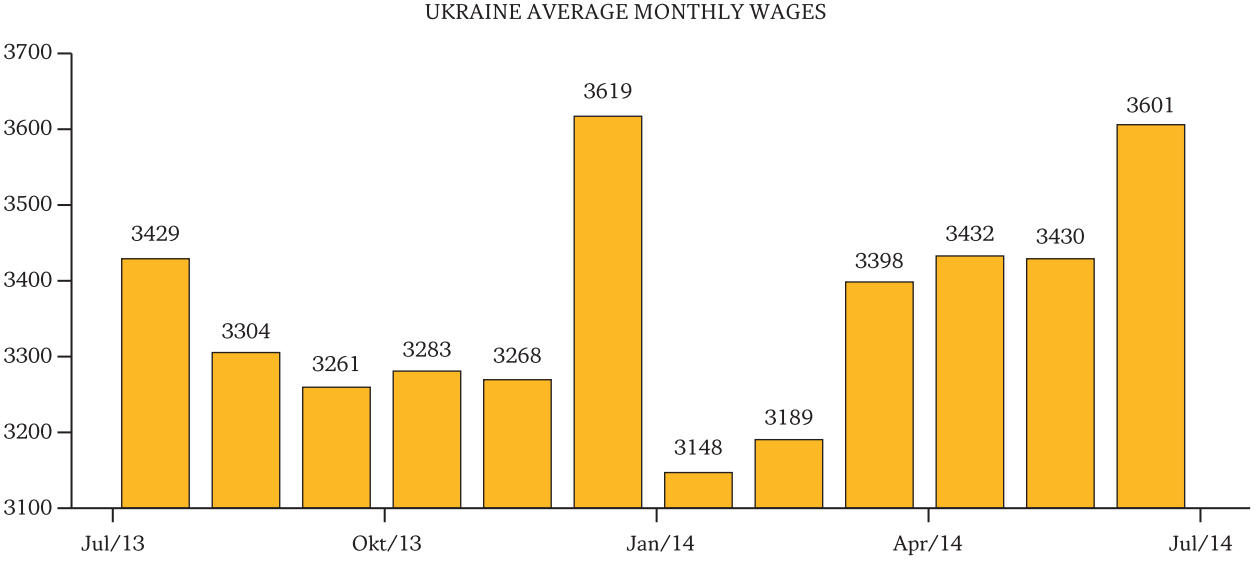


Source: *World Bank*

Ukraine is one of the countries which have a very high number of HCPs per a thousand of population, which is definitely one of the assets that Ukraine has. However, the supply of the low and middle level medical staff is low if compared to other countries.

Average salary

Average salary per month in Ukraine (2014)

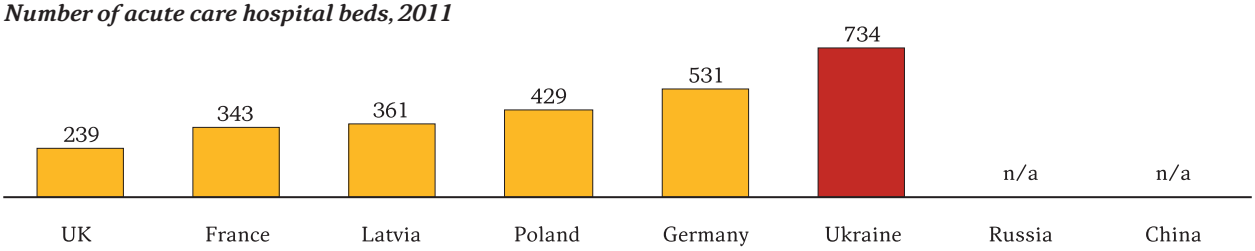


In national units per month (2014)

Countries	Wages	References	Previous	Highest	Lowest	Unit
Australia	1123,00	Jun/14	1114,20	1123,00	59,10	AUD
Brazil	2046, 31	Mar/14	2059,87	2457,22	1293,72	BRL
Canada	23,05	May/14	23,25	23,35	13,73	CAD
China	51474,00	Dec/13	46769,00	51474,00	445,00	CNY
Euro Area	736726,00	Feb/14	734055,00	736726,00	0,00	EUR Million
France	111,00	Feb/14	110,20	111,00	3,30	Index Points
Germany	113,90	May/14	113,30	169,50	12,10	Index Points
India	4,83	Dec/13	5,07	5,47	3,12	INR
Italy	105,30	Jun/14	105,20	118,10	25,40	Index Points
Japan	423,90	Jul/14	542,09	883,79	52,91	JPY THO
Mexico	282,59	Jun/14	283,27	283,27	124,36	MXN/DAY
Netherlands	133,10	Jul/14	132,80	133,10	76,60	Index Points
Russia	33563,00	Jun/14	32272,00	39648,00	0,00	RUB
South Korea	3256321,00	Feb/14	3126967,00	3256321,00	2460239,00	KRW
Spain	92,47	Jun/14	93,18	118,67	43,90	Index Points
Switzerland	308,00	Jun/13	305,00	308,00	121,00	Index Points
Turkey	165,11	Feb/14	162,99	165,11	57,77	Index Points
United Kingdom	477,00	Jun/14	478,00	485,00	306,00	GBP
United States	10,29	Jun/14	10,29	10,41	9,88	USD

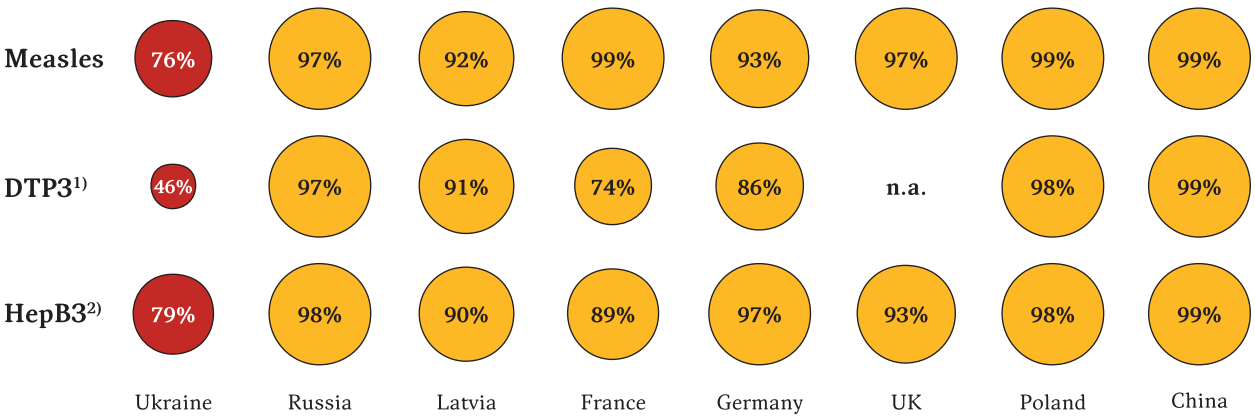
Service delivery

Number of acute care hospital beds, 2011



Source: *WHO*

Immunization coverage among 1-year-olds, %, 2012



Note: *1) DTP3 — Diphtheria tetanus toxoid and pertussis, 2) HepB3 — Hepatitis B*

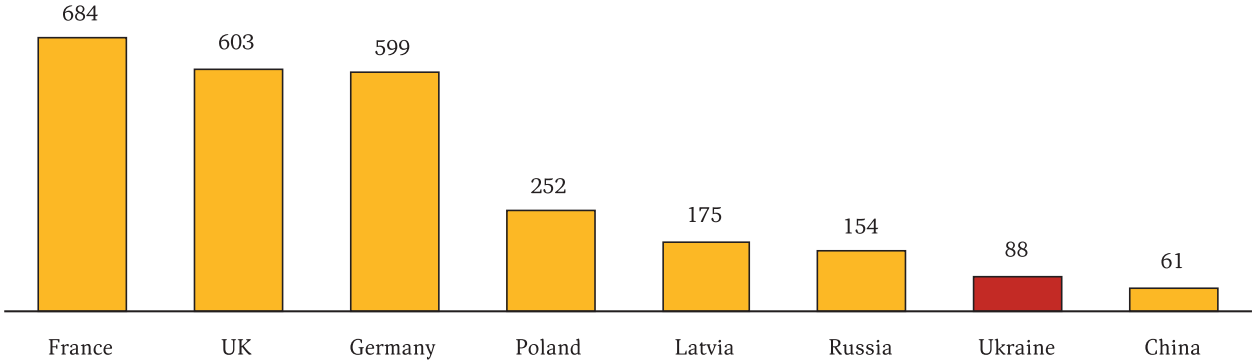
Source: *WHO*

In addition to the high number of HCPs per thousand of population Ukraine also has a high number acute hospital beds, these two factors could imply that there is a huge potential for the healthcare service delivery for the Ukrainian patients.

In terms of the immunization coverage among 1-year-olds, Ukraine is below that of the other countries, especially in terms of the HepB3 (as DTP3 rates seem in line with other countries?) immunization.

Access to medicines

Pharmaceutical sales per capita, USD, 2012



Source: *BMI*

Not surprisingly, because of the lower public and private healthcare expenditures, pharmaceutical sales per capita in Ukraine are low if compared to some of the developed and developing countries.

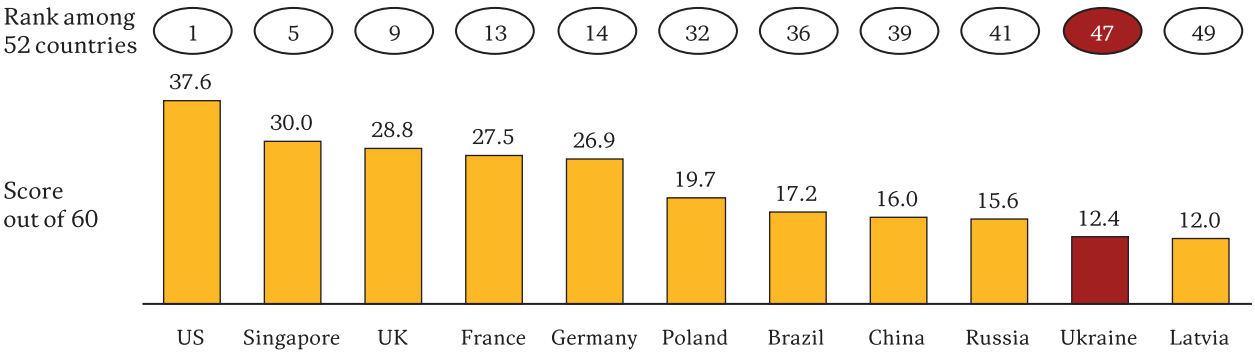
Comparison of the pharmaceutical industry in Ukraine to the international counterparts

In order to assess the competitiveness of the Ukrainian pharmaceutical industry we have compared the indicators characterizing its performance versus the leaders in the sector, as well as other developed and developing countries, across the pharmaceutical value chain elements, including:

- Overall country competitiveness
- Drug research capabilities
- Clinical trial environment
- Drug registration system
- Pharmaceutical manufacturing
- Healthcare financing
- Market access for new health technologies

Overall country competitiveness

Scientific American worldview biotechnology scorecard, 2013

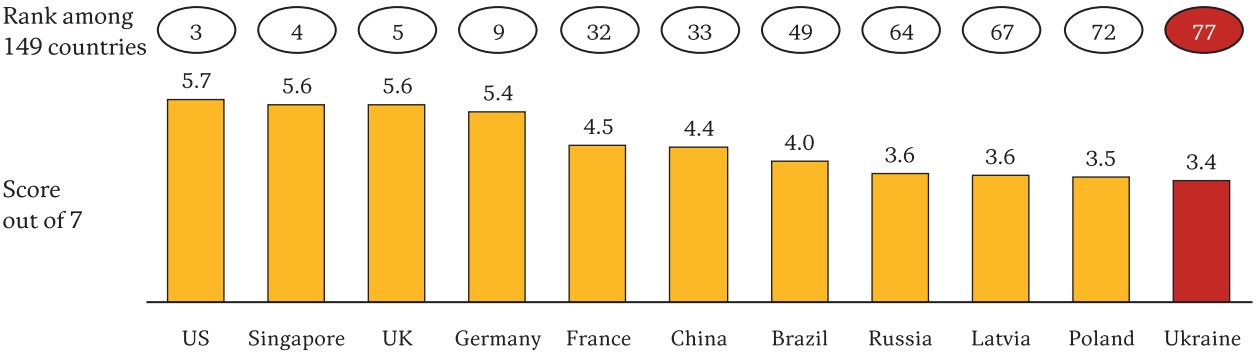


Source: *Scientific American*

The Scientific American Worldview Biotechnology Scorecard is a tool to measure the performance of the countries' pharmaceutical industries. Each country received a score in six categories — IP, Intensity, Enterprise Support, Education/Workforce, Foundations, and Policy and Stability — that each contained a set of components. Based on 0—10 scores, for lowest to highest, authors averaged the component scores to determine the category score. The overall innovation score represents a simple sum of the category averages, indexed to a score from 0—50. As the chart above shows, Ukraine clearly struggles to be competitive, being ranked #47 out of 52.

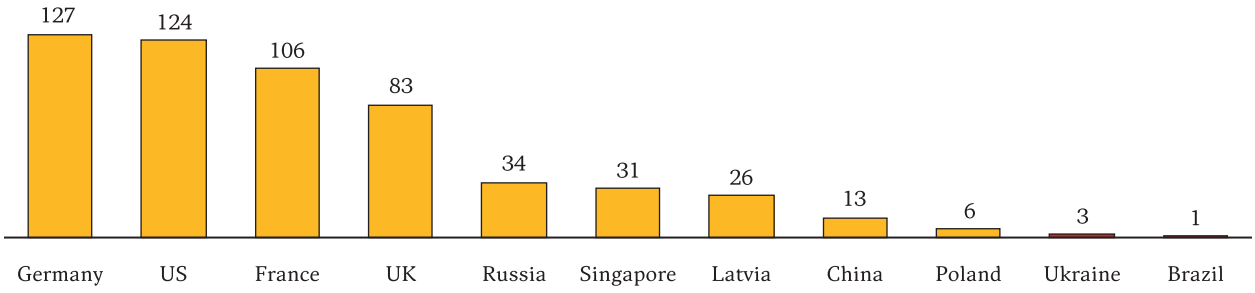
Drug research capabilities

Country's rank in the university-industry collaboration in R&D (Global Competitiveness Report), 2013—2014



Source: *Global Competitiveness Report 2013—2014*

Patent grants in pharmaceuticals, total count by applicant's origin per 1 M of citizens, 2007—2012

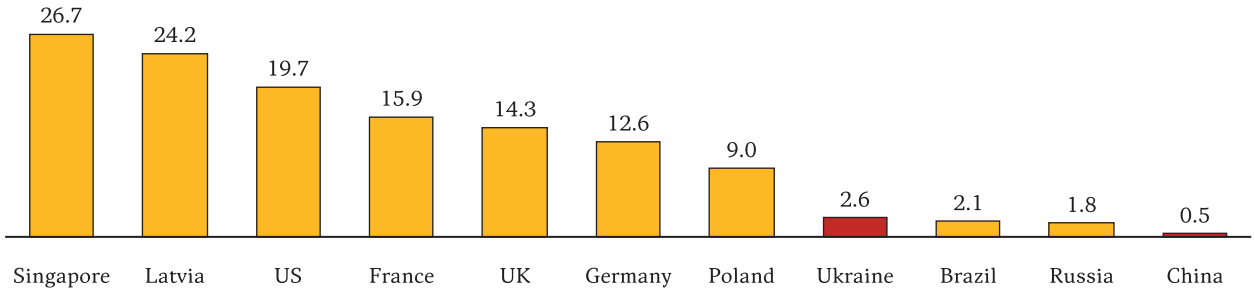


Source: *WIPO*

While after the soviet era Ukraine had and have numerous of biopharmaceutical research organizations, their results are not impressive — the patent grants in pharmaceuticals is very low and the Ukraine's rank in the university-industry collaboration in R&D (Global Competitiveness Report) is below other countries.

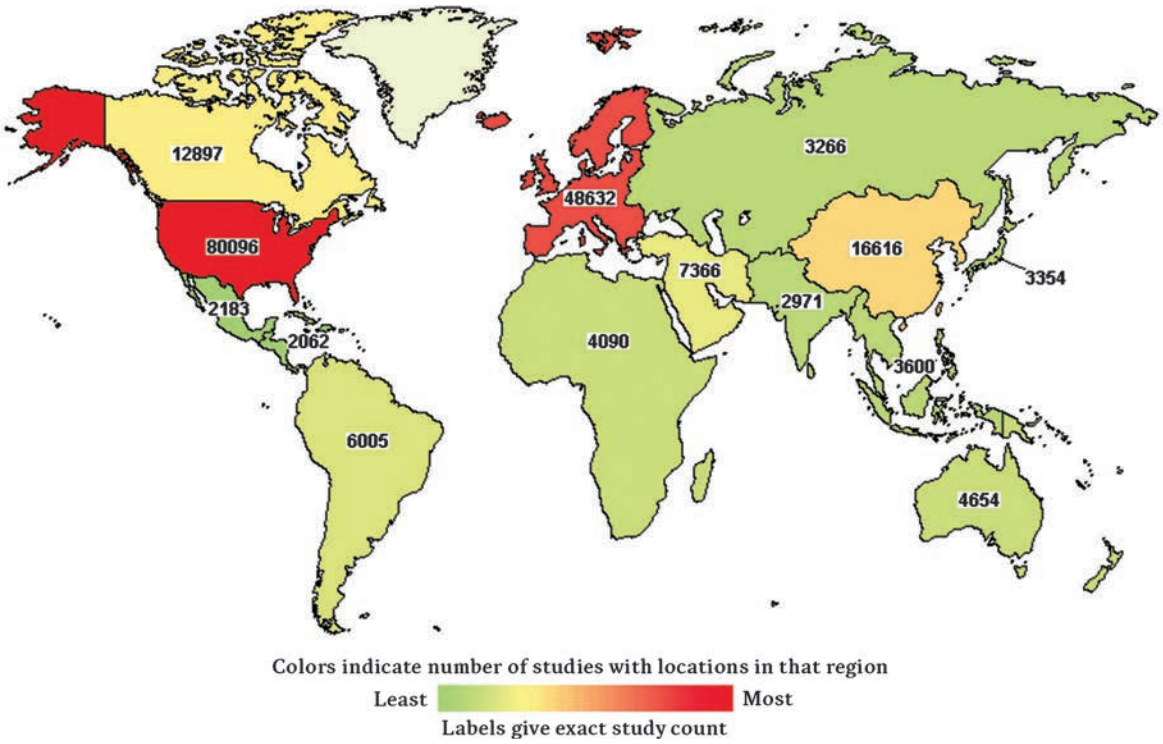
Clinical trial environment

Number of international interventional clinical trials initiated per Million of Population, 2012



Source: *clinicaltrials.gov*

Number of international interventional clinical trials initiated per Million of Population, 2012

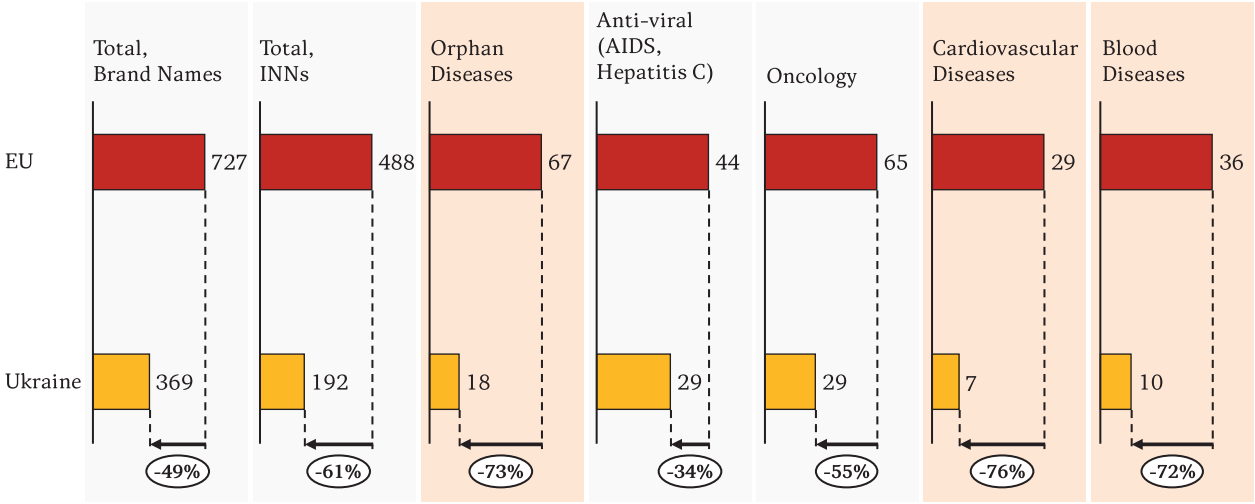


Source: *clinicaltrials.gov.ua*

Clinical trials, one of the biggest opportunities for the patients to get innovative treatment for free are not utilized in Ukraine. Coupled with high number HCPs and healthcare facilities, Ukraine could build a good environment in this field, attracting FDI and delivering innovative drugs to patients.

Drug registration system

Number of drugs registered in Ukraine vs. EU by type of drugs, 2013

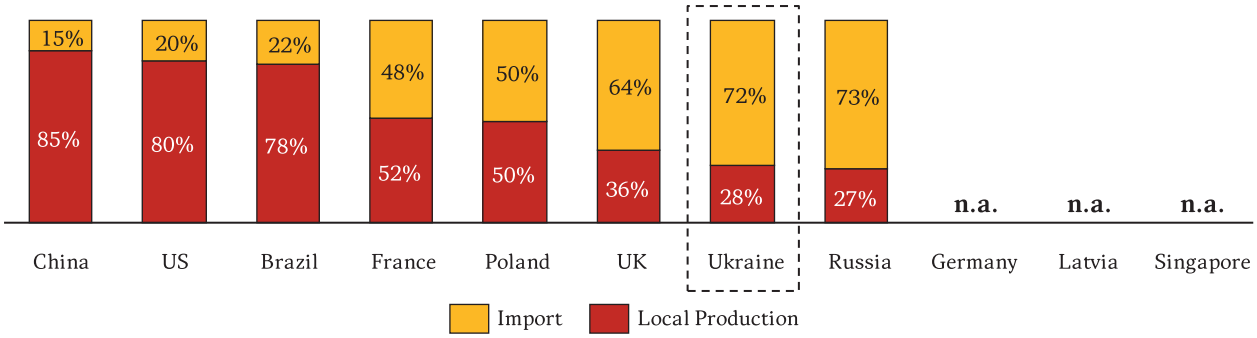


Source: *State Administration of Ukraine on Medicinal Products*

During the last 5 years, Ukraine undertook a significant effort in the harmonization of the drug registration regulations with that of the European Union, however, the number of the innovative drugs registered is still very low, which shows a development potential.

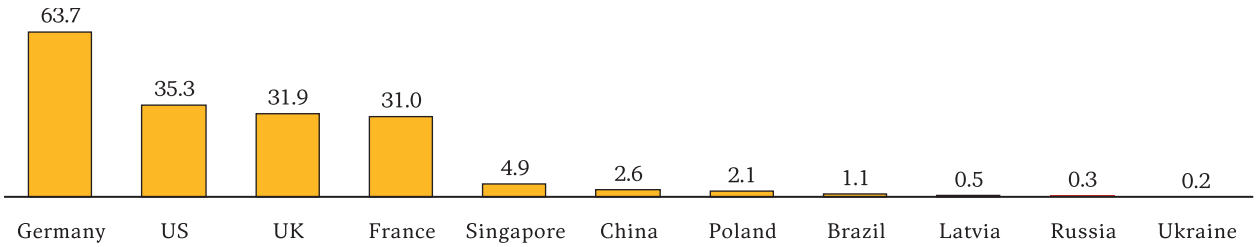
Pharmaceutical manufacturing

Share of local production in the pharmaceutical market, 2011, %, value terms



Source: *PwC estimates based on BMI and export.gov.ua*

Export of pharmaceutical products, 2011, USD B

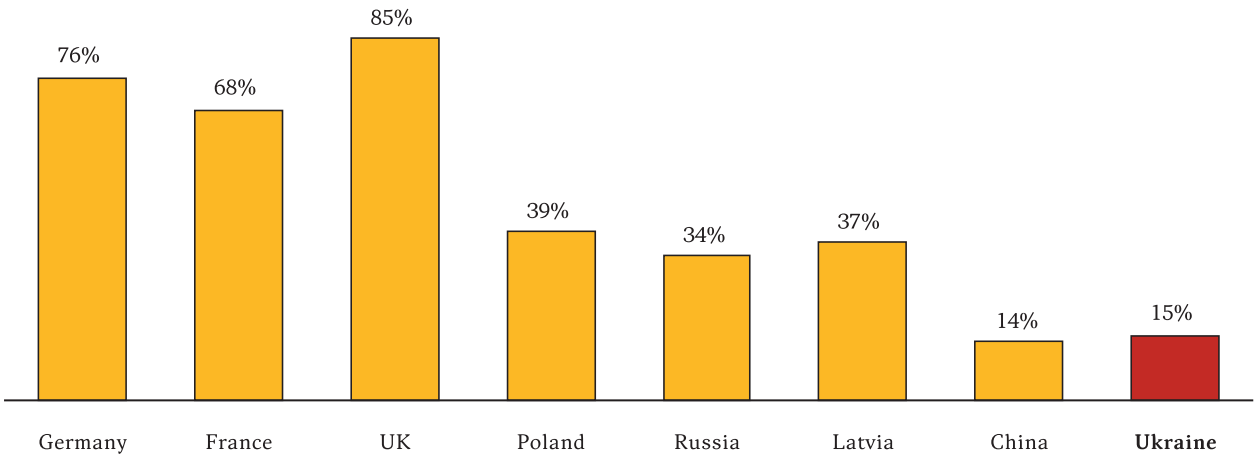


Source: *BMI*

Low share of local drug production in Ukraine is focused either on low value-added products (mostly non-branded generics) or on partial production of international drugs with the majority of high value-added drugs being imported. Even with the high GMP compliance of the Ukrainian pharmaceutical production facilities, Ukraine's export of pharmaceutical products is far below its real potential.

Healthcare financing

Share of government financing in total expenditure on pharmaceuticals (incl. hospital segment), 2011, %

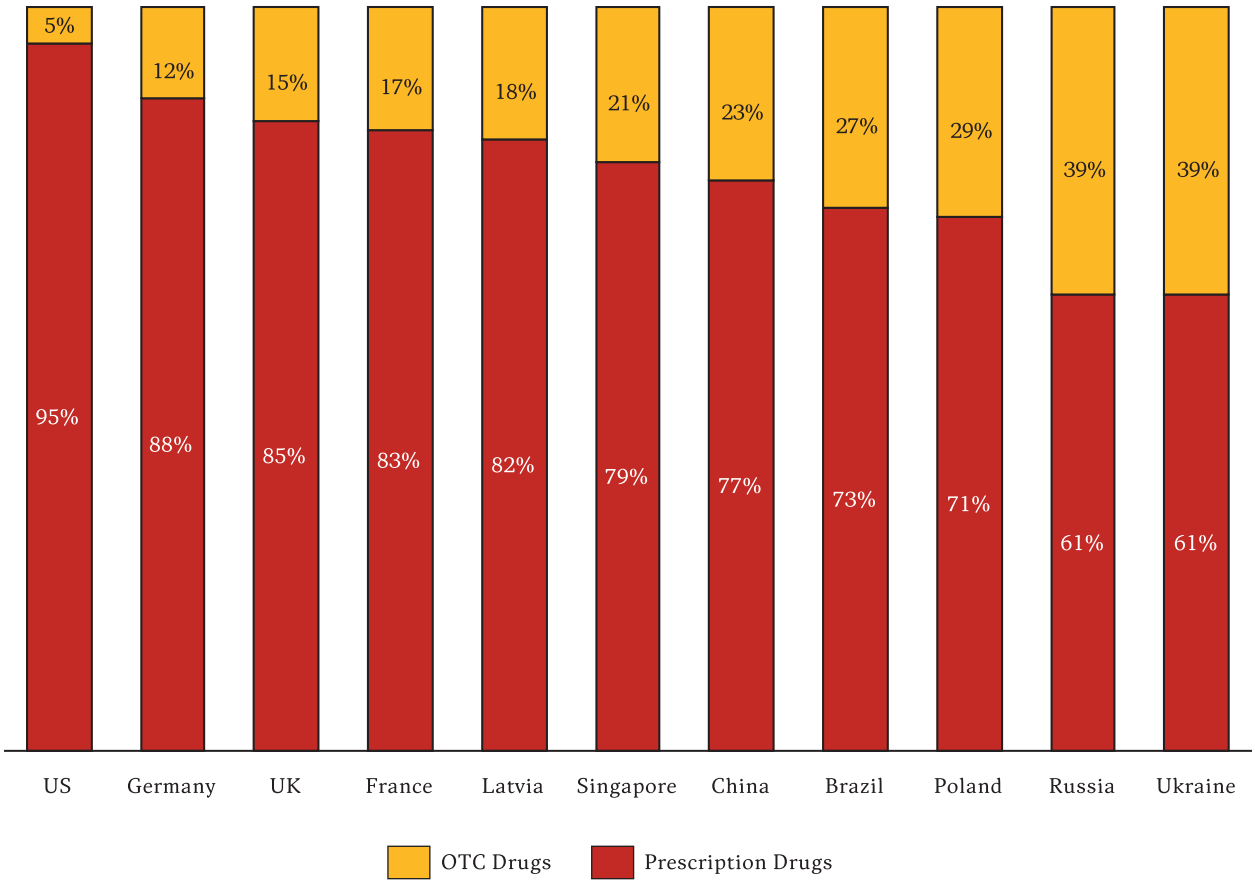


Source: *WHO*

Because of the low public healthcare financing, most of the pharmaceuticals in Ukraine are purchased on the private expenditures.

Market access for new health technologies

Share of prescription drugs in the market, 2012, %, value terms



Country's rank in IP rights protection (Global Competitiveness Report), 2013–2014

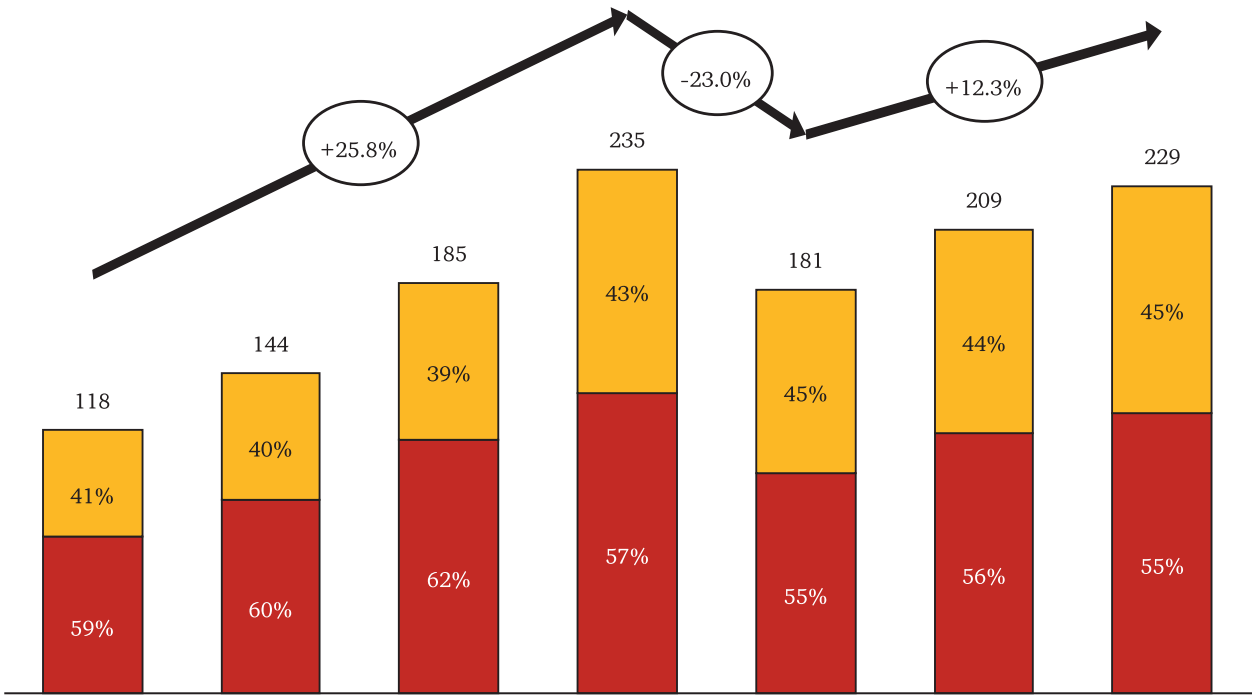
Source: *Global Competitiveness Report 2013–2014*

6 HEALTHCARE DEVELOPMENT IN UKRAINE

Progress in the health outcomes in Ukraine

Since the early 2000s the Ukrainian government has made significant efforts to improve the healthcare system of the country. Supported by the economic growth health expenditure in Ukraine was rising fast in 2005—2008 with the fall in 2009 due to the economic recession and the following recovery in 2010 and 2011.

Health expenditure per capita in Ukraine, constant 2005 USD



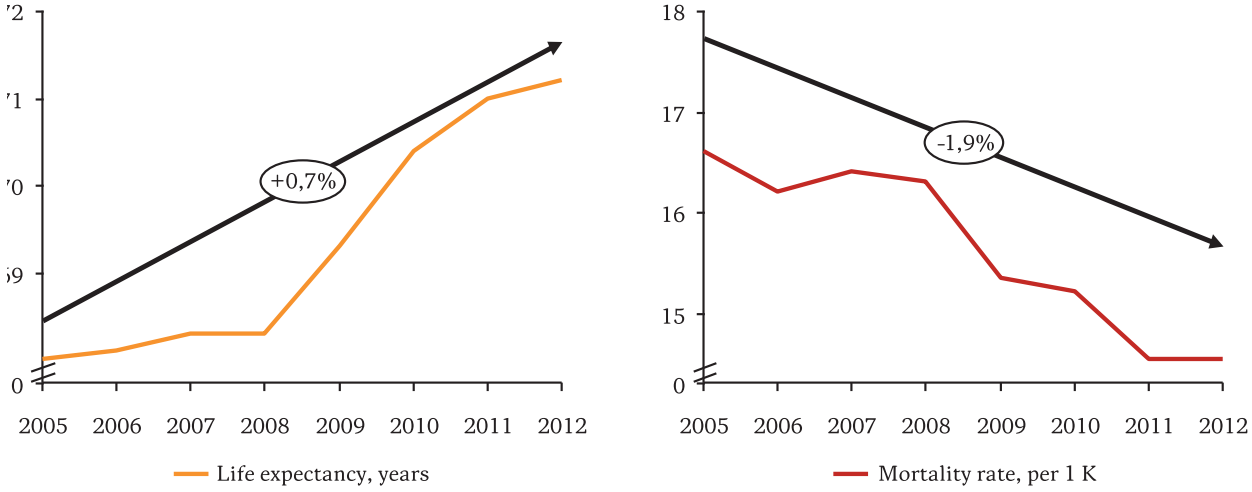
Source: *State Statistics Service of Ukraine; PwC analysis*

In addition to increase in the healthcare financing, government has launched several strategic programs on separate diseases and specific health issues, including:

- National Program against cancer in the 2007—2016 year
- National Program "Diabetes mellitus" in 2009—2013
- National Program for HIV prevention, treatment, care and support for people suffering from HIV and AIDS for 2009—2013
- National Program "Reproductive Health of Nation" for the period up to 2015
- National Program of Immunization and protection against infectious disease in 2007—2015

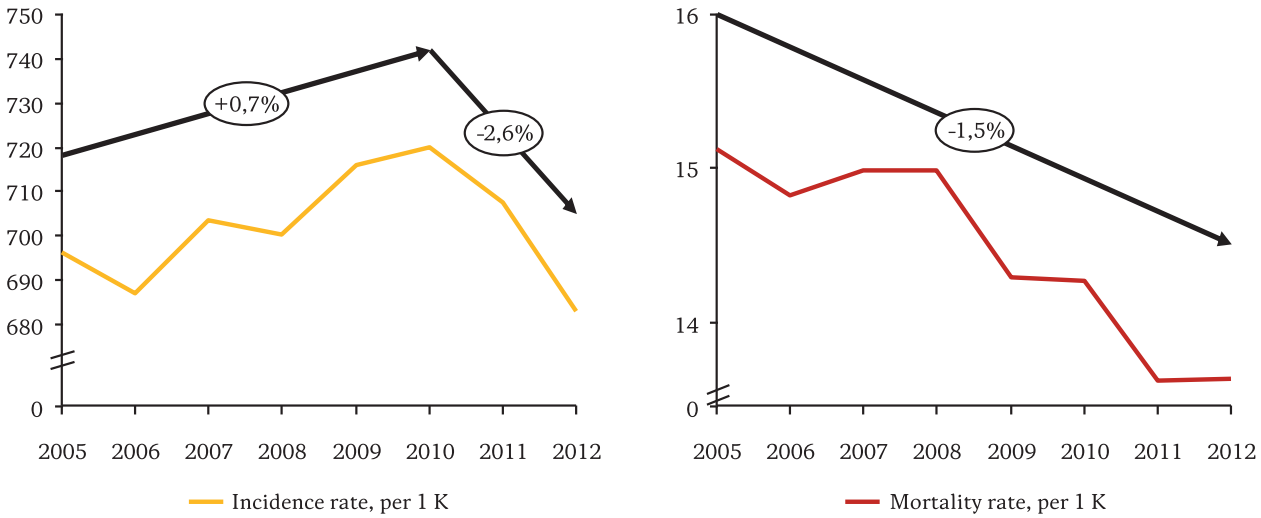
Significant increase in the healthcare financing, as well as the focus of the government on the specific health issues has resulted in significant improvement of the life expectancy, overall mortality rate and mortality rates from specific diseases.

Life expectancy at birth and total mortality rate in Ukraine



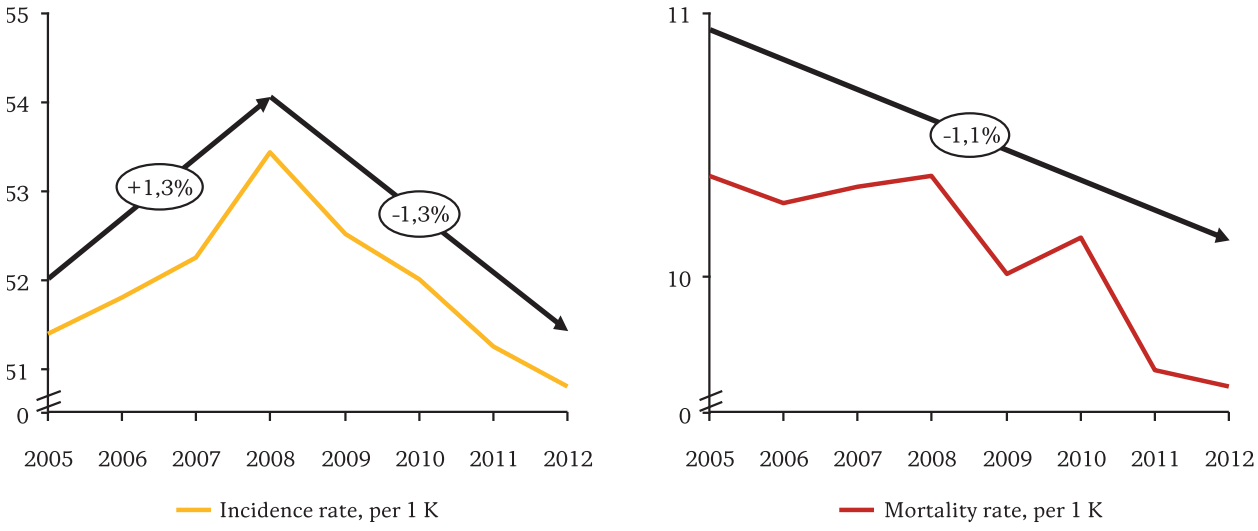
Source: *State Statistics Service of Ukraine*

Incidence rate and mortality rate in Ukraine — All diseases



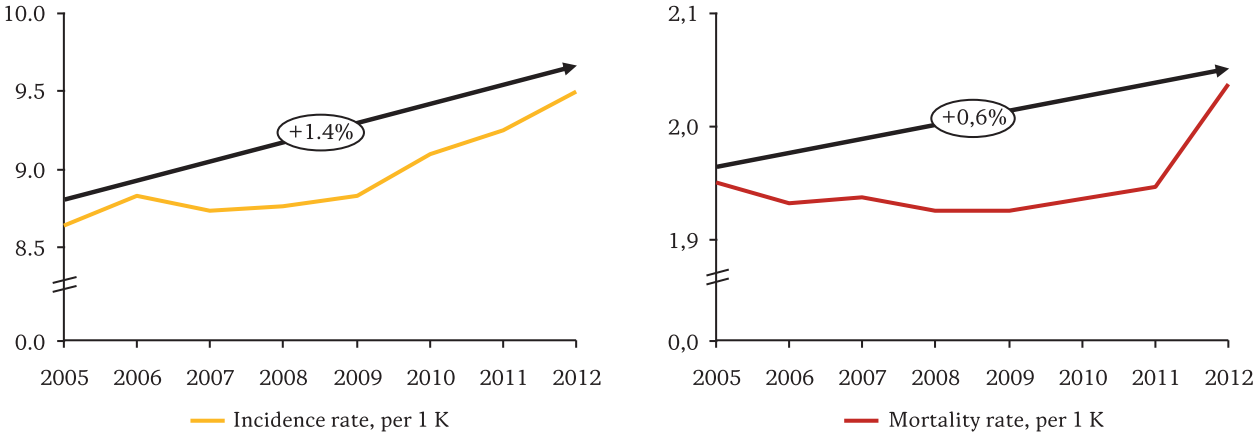
Source: *State Statistics Service of Ukraine*

Incidence rate and mortality rate in Ukraine — Cardiovascular diseases



Source: *State Statistics Service of Ukraine*

Incidence rate and mortality rate in Ukraine — Neoplasms



***Source**: State Statistics Service of Ukraine*

Overall, improvement in treatment of all diseases in Ukraine resulted in ~70,000 less people dying in Ukraine from all diseases in 2011 compared to 2005. Reduction of the mortality rate from the cardiovascular diseases accounted for more than a half of this improvement. No significant improvement was observed in the mortality rate form the neoplasms which could be associated with the insufficient patient access to the required cancer medications.

Government programs in the healthcare sector

Despite significant progress in terms of improvement of the key life indicators there are still a lot of issues across the healthcare system in Ukraine (please see Comparison of the Ukrainian Healthcare System to International Counterparts). This is largely explained by the fact that until recent time there has been no comprehensive strategy of the healthcare system reform in Ukraine. In 2010 the Ukrainian government outlined the ambitious plan of the healthcare reform under the Program of the Economic Reforms in Ukraine for 2010—2014 and its implementation plans adopted annually.

In 2012, in line with the targets of the Implementation Plans of the Program of the Economic Reforms in Ukraine the Ministry of Health of Ukraine has developed a comprehensive health policy document "Health 2020: Ukrainian Dimension", which outlines the policy directions for development of the health system of Ukraine across all its elements. The draft of the State Program "Health 2020: Ukrainian Dimension" was approved by the government of Ukraine and was submitted to Verkhovna Rada in 2013.

To provide a high level assessment of the government programs of the healthcare reforms we have analyzed the two documents mentioned above based on the WHO's framework for healthcare system analysis. According to this framework a well-functioning healthcare includes the following six key elements:

1. Leadership and Governance
   - The national health policy and strategy
   - The policy-making process
2. Information System
   - National health statistical reporting system
   - IT-systems and tools for utilization of the relevant information
3. Health System Financing
   - System to raise sufficient funds for health fairly
   - System to pool financial resources across population groups to share financial risks
   - Financing governance system and clear operational rules to ensure efficient use of funds
4. Human Resource for Health
   - Sufficient number and the right mix of the healthcare professionals
5. Access to Medical Products
   - Medical products regulatory system
   - Medical product reimbursement system
   - System to promote rational prescribing
6. Service Delivery
   - Networks of close-to-client primary care with the back-up of specialized and hospital services, responsible for defined populations

- Provision of a package of benefits with a comprehensive and integrated range of clinical and public health interventions, that respond to the full range of health problems of the population
- Standards, norms and guidelines to ensure access and essential dimensions of quality

The overview of the key government initiative in terms of the healthcare system development under the Program of the Economic Reforms for 2010—2014 and the State Healthcare Programs across the six elements of the healthcare is provided below.

Program of the Economic Reforms in Ukraine for 2010—2014 (and Action Plans on its implementation)

Element of the Health System	Overview of the Key Initiatives
1. Leadership and Governance	• Development and adoption of the comprehensive health policy document
2. Information System	• Development and implementation of the electronic patient registers • Implementation of the IT-based document flow in the healthcare facilities • Optimization of the statistical reporting of the healthcare facilities
3. Health System Financing	• Improvement of the healthcare budget planning including distribution between the levels of care • Introduction of the contracts for provision of the healthcare services to the population between the government healthcare budget holders and the healthcare facilities • Introduction of the fee-for-service and pay-for-performance payment models in the primary care • Development of the DRG-based payment model for the secondary care with the priority of the groups most common in Ukraine • Increase of the excise duties on the alcohol and tobacco products and allocation of the additional funding to the healthcare
4. Human Resources for Health	• Ensuring sufficient availability of general practitioners for primary care through post-graduate education of the graduates of the medical universities and retraining of the physicians of other specialties • Development of the standards for staffing of the secondary and tertiary healthcare facilities and proper planning of the required number of the healthcare professionals based on the standards
5. Access to Medical Products	• Improvement of the medicines prescription and distribution system • Improvement of the state regulation of drug prices • Introduction of the Good Regulatory Practice in the sphere of the pharmaceutical circulation • Development and implementation of a procedure for planning the volumes of the state drug procurement • Gradual introduction of the drug reimbursement system for certain diseases
6. Service Delivery	• Development of the infrastructure for provision of the primary care including creation of the sufficient number of the ambulatories and their equipment • Development of the infrastructure for emergency care including creation of the sufficient number of the emergency care facilities and their equipment, development of the emergency care car fleet and maintenance of the proper condition of the roads that are critical for functioning of the emergency care service • Development of the infrastructure for secondary and tertiary care with the proper planning of the number and location of the healthcare facilities and their equipment and optimization of the hospital bed capacity with the population needs • Development and implementation of the clinical pathways and medical treatment standards for conditions most common in the medical practice in Ukraine

State Healthcare Program (not adopted yet)

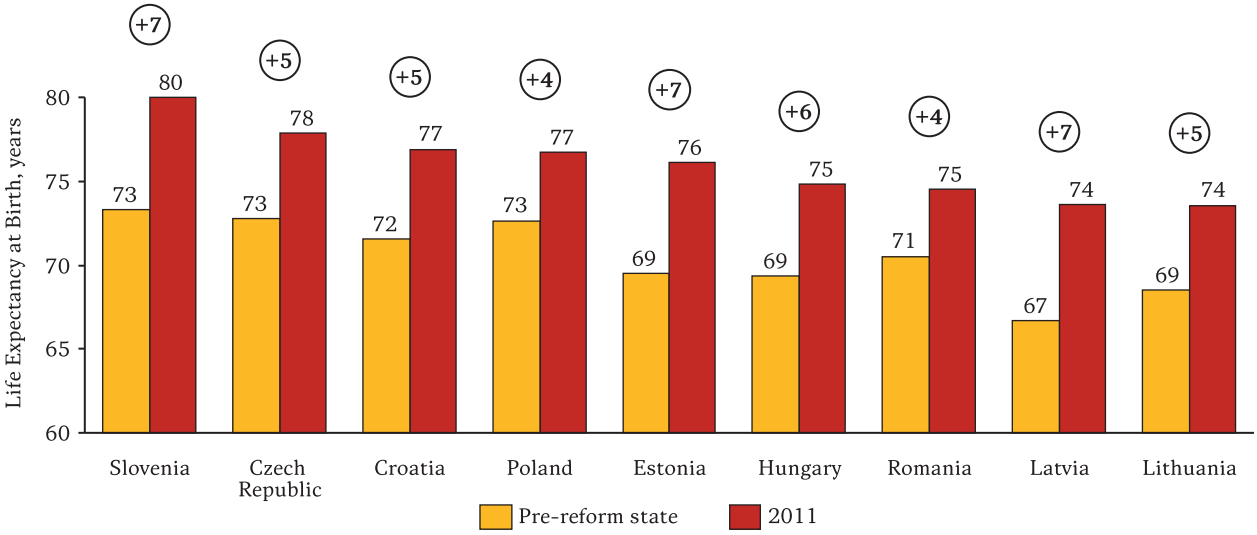
Element of the Health System	Overview of the Key Initiatives
1. Leadership and Governance	• Ensuring cooperation between the various government bodies, medical societies and patients in the area of health policy development and implementation • Creation of the Coordination Council under the Cabinet of Ministers of Ukraine to ensure cross-sectoral comprehensive approach to implementation of the State Healthcare Program • Monitoring of the implementation of the State Healthcare Program against a set of defined KPIs • Ensuring implementation of the initiatives under the Program of the Economic Reforms in Ukraine for 2010—2014 • Ensuring international cooperation in the healthcare
2. Information System	• Development of the integrated data bases on the provision of the healthcare services and the health condition of the population • Development and implementation of the electronic patient registers, IT-based document flow in the healthcare facilities, electronic prescription system, electronic patient waiting lists, registers of the healthcare facilities and healthcare professionals
3. Health System Financing	• Introduction of the contracts for provision of the healthcare services to the population between the government healthcare budget holders and the healthcare facilities • Introduction of the fee-for-service and pay-for-performance payment models for healthcare professionals • Introduction of the public-private partnerships in the healthcare • Development of the voluntary medical insurance
4. Human Resources for Health	• Introduction of the benefits for healthcare professionals such as provision of the free apartments • Improvement of the education of the healthcare professionals in line with the adopted medical treatment standards • Planning of the required number of the primary care professionals and creation of the required number of the network of the training centres for online education and continuing education of the healthcare professionals • Introduce joint programs of the education of the healthcare professionals between research institutions, clinical bases, higher education institutions and healthcare facilities
5. Access to Medical Products	• Procurement of the required amount of the vaccines and vaccine vial monitors • Procurement of the required amount of the medicines and medical devices for free drug provision in line with th e regulation

6. Service Delivery	• Development and implementation of the clinical guidelines, clinical pathways and medical treatment standards • Optimization of the network of the healthcare facilities in line with the population needs • Improvement of the health and care for specific groups of population — Special initiatives to improve the health of the target social groups including mothers, infants, children, young people, seniors and migrants — Improvement of the health of working population through initiatives targeting creation of the healthy work environment — Improvement of the care and life conditions for disabled people; prevention of children disability and rehabilitation of disabled • Improvement in prevention, diagnostics and treatment of certain disease groups: — Improvement of the diagnostics, prevention and treatment of the mental conditions through patient education, preventive examinations, professional education and development of the network of the healthcare facilities — Improvement of the immunization system and prevention of the infectious diseases through procurement of the vaccines in line with the immunization schedule, introduction of new vaccines, enforcement of the immunization schedule and seasonal immunization, patient education and international cooperation in the prevention of the infectious diseases — Improvement of the diagnostics, prevention and treatment through development of the specialized treatment and diagnostics centres, introduction of the screening programs and individual monitoring programs for people with the risk of diseases and introduction of the system of rehabilitation of the patients with the chronicle non-communicable diseases • Improvement of the health care provision across the different levels of care: — Priority development of the primary care through implementation of the family medicine, introduction of the mechanisms of managing patient flows and optimization of the network of the primary care facilities — Improvement of the provision of the emergency care — Improvement of the provision of the secondary and tertiary care through development of the network of the healthcare facilities, including acute care, non-emergency, rehabilitative care and palliative care hospitals, specialized centres and diagnostics centres — Development of the rehabilitative care — Development of the palliative care • Development of the blood service including improvement of the regulation, blood screening, promotion of donorship and other • Development of the specialized services including toxicological, laboratory and endoscopic services and forensic medical examinations • Promotion of the healthy life style and patient education on disease prevention and health maintenance through the mass media, information campaigns, phone 'hot lines' and specialized health centres and health schools • Maintenance of the healthy environment including quality of water, air and food through improvement of the regulation and control

Ukraine is uniquely positioned to leverage the experience of other CEE countries that already went through the health system reforms in 1990s—2000s. CEE countries that went through the health system reforms show different degrees of success in implementation of the initiatives across the elements of the healthcare system. However, all of the countries demonstrate significant progress in terms of the key life indicators (please see the chart below).

Despite some peculiarities, most of the healthcare reforms in the CEE countries implied the similar set of the initiatives across the health system. Comparison of the current government plans on the health reform in Ukraine with the key elements of the health reform based on the CEE countries' experience demonstrates high-level alignment of the policy directions (please see below).

Increase in the life expectancy in the selected CEE countries that went through the health system reforms



Source: *World Bank*

Comparison of the Current Government Plans on the Healthcare Reform in Ukraine with the Common Elements of the Reforms Based on the CEE Countries Example

Element of the Health System	Key Elements of the Reform based on the CEE Countries' Experience	Alignment between the Healthcare Programs in Ukraine and Experience of other CEE Countries that Went through the Healthcare System Reforms
1. Leadership and Governance	• Development of the comprehensive health strategy	Provided under the State Healthcare Program
	• Cooperation between the various government bodies, medical societies and patients in the area of health policy development and implementation	
2. Information System	• Development of the statistical reporting system	Provided under the State Healthcare Program and the Program of the Economic Reforms in Ukraine for 2010—2014
	• Implementation of the IT-systems in the healthcare including electronic patient registers, IT-based document flow in the healthcare facilities, electronic prescription system and electronic patient waiting lists	
3. Health System Financing	• Development of the mandatory health insurance with the employee / employer contributions as a main source of financing and the contracts on the provision of the healthcare services concluded between the healthcare facilities and the insurance fund(s)	Is not provided under the State Healthcare Program or the Program of the Economic Reforms in Ukraine for 2010—2014, however the draft of the Law on the mandatory medical insurance in Ukraine is developed
	• Development of the voluntary health insurance	Provided under the State Healthcare Program
	• Increase in the excise duties on alcohol and tobacco products with additional financing allocated to the healthcare	Provided under the Program of the Economic Reforms in Ukraine for 2010—2014
	• Introduction of the fee-for-service and pay-for-performance payment models in the primary care and DRG-model in the secondary care	Provided under the State Healthcare Program and the Program of the Economic Reforms in Ukraine for 2010—2014

4. Human Resources for Health	• Provision of the specialist trainings in the family medicine for graduates of the medical universities and re-training of the physicians of other specialties	Provided under the State Healthcare Program and the Program of the Economic Reforms in Ukraine for 2010—2014
	• Development of the continuing medical education system	Introduced by the Order of the Ministry of Health of Ukraine № 484 from 07.07.2009, however some gaps in the system still exist (please see the Continuing Medical Education section)
5. Access to Medical Products	• Harmonization of the clinical trial regulation with the international recommendations	The regulation is significantly harmonized, however some gaps in the clinical trial regulation still exist (please see the Clinical Trial Environment section)
	• Harmonization of the drug registration system with the EU rules	The system is significantly harmonized, however some gaps in the system still exist (please see the System to Approve New Drugs section)
	• Development of the drug reimbursement system	Some initiatives are provided under the Program of the Economic Reforms in Ukraine for 2010—2014 and implemented under the Anti-hypertension Pilot Project, however still no plan for development of the universal drug reimbursement system exist
	• Harmonization of the intellectual property rights regulation with the EU rules	Significant steps towards harmonization of the intellectual property rights with the WTO rules, however gaps in the IP rights regime still exist (please see the Intellectual Property Rights Regime section)
6. Service Delivery	• Optimization of the network of the healthcare facilities and the hospital bed capacity across the different levels of care in line with the population needs	Provided under the Program "Health 2020: Ukrainian Dimension" and the Program of the Economic Reforms in Ukraine for 2010—2014
	• Development and implementation of the clinical guidelines and pathways	
	• Enforcement of the immunization schedules in line with the WHO guidelines	
	• Introduction of the screening Programs for most critical non-communicable diseases	
	• Enforcement of the primary care physicians' gate-keeping function	

Ukraine has taken significant steps towards ensuring patient access to medicines in line with the other CEE countries' experience, however there is still ground to cover in terms of the improvement of the pharmaceutical industry regulation and especially in terms of development of the drug reimbursement system.

In addition, development of the pharmaceutical sector in Ukraine would require significant amount of foreign direct investment (FDI). To attract its share from FDI in the innovative pharmaceutical sector, Ukrainian pharmaceutical regulations should provide favorable conditions competitive with other countries regarded as priority destinations for pharmaceutical FDI.

7 KEY AREAS FOR IMPROVEMENT IN THE PHARMACEUTICAL SECTOR OF UKRAINE

In order to attract significant amount of pharmaceutical FDI and develop competitive innovative pharmaceutical industry Ukraine needs to ensure favourable policy environment in line with the experience of the best practice countries such as Ireland and Singapore.

To identify key gaps and issues in the Ukrainian pharmaceutical industry environment, we used the following approach to enable us to develop a holistic picture:

- We partnered with the Pugatch Consilium Ltd. to launch the Biopharmaceutical Competitiveness Index (BCI) Survey among industry executives and government officials;
- We conducted face-to-face interviews with industry experts;
- We analysed and cross-compared international best practises

Biopharmaceutical Competitiveness Index (BCI) Survey

The objective of the BCI Survey is to provide a comprehensive snapshot of different countries' attractiveness for foreign direct investment and innovation in the pharmaceutical industry, derived from the firsthand knowledge of experts and investors operating in each country. Based on a statistical analysis of survey answers each country evaluated receives a score (out of a total of 100). These scores are used to rank countries and benchmark their performance vis a vis other countries, both generally and in specific areas. Ultimately, the aim of the index is to provide a tool for informing and enhancing policy-making in the pharmaceutical and healthcare field.

The BCI Survey asks executives and experts operating "on the ground" a wide range of in-depth questions about the performance of the country in which they operate. Their answers are then statistically analyzed to produce a quantitative index of that country's competitiveness in various areas of the biopharmaceutical-innovation pipeline. By drawing on firsthand insight from locally stationed biopharmaceutical executives, the BCI's survey-based approach represents a unique and innovative method for evaluating the biopharmaceutical-investment attractiveness of countries.

Each section of the survey was designed to evaluate a country's performance in a different area of the "ecosystem" in which the biopharmaceutical innovation life-cycle takes place.

Accordingly, the survey begins with addressing the quality of the science base and infrastructure and goes on to thoroughly analyse clinical and manufacturing capabilities, the regulatory environment and market conditions. In all, it seeks to provide a comprehensive, relevant and accurate picture of a country's performance at different segments of the biopharmaceutical "pipeline", and hence it's global competitiveness and attractiveness for investment.

Blocks of the BCI Survey

BCI Survey Section	Description
Scientific Capabilities & Infrastructure	The quality of personnel, technologies and facilities in biopharmaceutical research forums in the country, and the ability to leverage these to translate discoveries into products
Clinical Environment	The ability of research institutions in the country to conduct clinical research in a high quality and efficient manner

Manufacturing & Logistics	The ability to manufacture and distribute health technologies efficiently and to a high standard in the country
Regulatory Framework	The ability of the regulatory system in the country to ensure that only high quality, safe health technologies enter the market, yet do so in a timely manner
Healthcare Financing	The ability of new health technologies to access the market via the reimbursement system in the country in an efficient manner and at an acceptable price
Effective Market Access Activities	The ability to effectively provide prescribers and patients in the country with access to new health technologies and to maintain the required term of market exclusivity for such technologies
Overall Market Conditions	The degree to which general political, macro-economic and bureaucratic conditions facilitate or hinder biopharmaceutical investment in the country
General Impression	Overall attractiveness of the country to biomedical investment

BCI Survey results and interpretation

In order to have the most comprehensive and balanced picture, we have interviewed 34 individuals from four different segments of stakeholders — international and domestic pharmaceutical companies, academia and government officials. We have received responses from 27 organizations distributed as follows:

Total of 23 Responses to the BCI Survey	
Respondents from the Pharmaceutical Business	**Government Respondents**
17 Responses from 10 Companies	**6 Responses from the Government Bodies**
ACC Ukraine THE CHAMBER OF COMMERCE; APRaD Association of Pharmaceutical Research and Development; abbvie; AstraZeneca; Baxter; Bayer; Boehringer Ingelheim; Lilly; MSD; novo nordisk®; Pfizer; Roche; SANOFI; SERVIER	State Administration of Ukraine on Medicinal Products Ministry of Health of Ukraine

Key takeaways of the BCI Survey

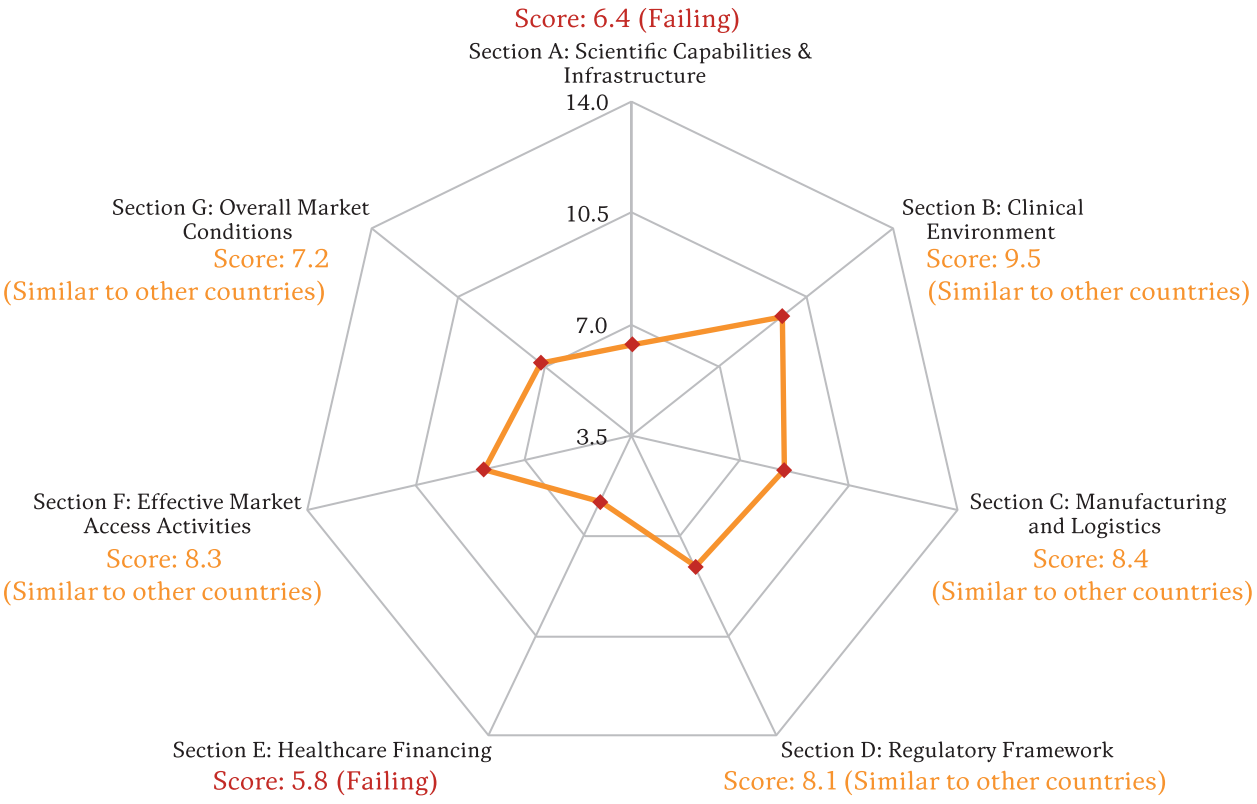
The overall scores give an idea of Ukraine's performance and relative competitiveness versus other countries. Countries with a score above 80 enjoy a competitive position relative to other countries, countries with scores of 70—80 possess reasonable competitiveness, scores of 60—70 indicate a limited ability to compete and those scoring 50—60 struggle.

The results by section provide a more "drilled-down" impression of executives' views of the performance of their country in the seven categories. As the detailed scores show, countries perform well in some areas but lag in others. For example, almost all countries performed the lowest in healthcare financing. Countries with the lowest overall scores also experience problems with additional areas, including scientific capabilities, manufacturing and logistics, and effective market-access activities. The table in the end of this section includes colour-coded indicators of a country's performance compared to others.

Ukraine's overall score in 2013 in the BCI survey is 55.8 staying and is characterized as "struggling to compete".

Ukraine's score in most of the sections of the BCI survey is characterized as similar to other countries. However, the most significant gaps are identified in the Scientific Capabilities and Infrastructure and the Healthcare financing sections with the scores characterized as failing. Low score in the Scientific Capabilities and Infrastructure indicate the limited ability of the Ukrainian research institutions to conduct local research in pharmaceuticals and a critical need for foreign direct investment in the area of pharmaceutical R&D, as well as for the strong cooperation between the government, research institutions and the international pharmaceutical companies. Failing score in the Healthcare Financing section is explained by the lack of the adequate healthcare financing, comprehensive drug reimbursement system and the problems in the overall efficiency of the healthcare system, which indicates a need for implementation of the healthcare reforms initiated by the government. Overall, BCI survey results indicate that improvements are required across the whole value chain of the pharmaceutical industry.

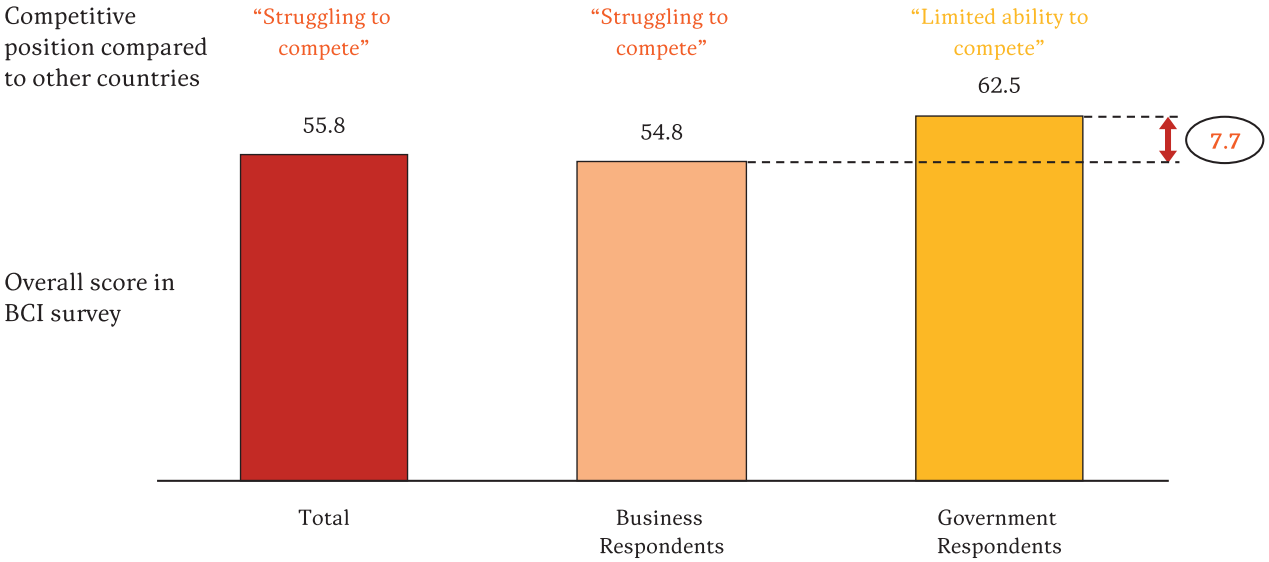
Ukraine's BCI scores by section (from 3.5 to 14.0), 2013



Analysis of the BCI survey results also shows that among the survey respondents, government representatives are materially more positive about the Ukrainian pharmaceutical industry competitiveness than respondents from the pharmaceutical business. Such a situation indicates that there is some level of misalignment between the state and the private sector on the challenges and op-

portunities in the pharmaceutical industry. To address this important difference in perceptions affecting investment, we conclude that there is a critical need for dialogue between the government and pharmaceutical industry representatives. This continuous and structured dialogue should aim to understand shortcomings, and develop reforms or policies addressing obstacles that hinder Ukraine's potential and global competitiveness in this strategic sector.

Overall Ukraine's BCI survey results 2013 by respondent type



Comparison of the BCI Survey for Ukraine and other countries (both overall and by sections) is provided below.

The Biopharmaceutical Competitiveness Index (BCI) Survey (among business respondents only), 2012–13

	Scientific Capabilities & Infrastructure	Clinical Environment	Manufacturing & Logistics	Regulatory Framework	Healthcare Financing	Effective Market Access Activities	Overall Market Conditions	General Impression	Score	Relative Competitiveness
Denmark	11.58	11.92	13.75	12.83	9.42	11.42	10.58	1.67	83.17	Strongly Competitive
Switzerland	11.14	9.36	12.21	11.79	8.29	11.14	12.07	1.57	77.57	Reasonably Competitive
US	11.75	10.25	10.83	10.33	9.75	10.58	10.50	1.92	75.91	
Canada	10.36	10.71	12.25	11.79	7.82	9.21	11.54	1.64	75.32	
Sweden	10.38	10.50	11.63	12.13	9.00	9.25	10.38	1.63	74.90	
Norway	8.77	9.50	12.05	10.64	8.64	9.32	11.09	1.41	71.42	
Israel	10.15	10.73	11.19	9.08	8.50	8.85	9.92	1.54	69.96	Limited Ability to Compete
Poland	6.50	11.83	12.00	11.00	8.50	8.17	9.67	1.33	69.00	
Argentina	8.43	9.71	9.14	9.21	8.43	9.36	10.86	1.50	66.64	
UAE	6.38	8.96	10.27	9.46	7.62	9.36	11.92	1.62	65.59	
South Africa	7.67	10.75	10.17	8.67	6.83	10.00	9.33	1.50	64.92	
Lithuania	7.00	10.33	10.17	10.00	7.83	8.83	8.83	1.67	64.66	
Greece	7.36	9.54	9.57	9.18	7.50	9.64	8.57	1.39	62.75	

China	8.17	8.83	8.50	7.50	6.50	8.50	10.17	1.67	59.84	Struggling to Compete
Russia 2013	7.28	9.50	8.16	7.92	6.45	8.10	9.47	1.56	58.37	
Saudi Arabia	5.63	7.83	9.17	8.46	6.63	7.71	10.42	1.46	57.31	
Ukraine 2013	5,93	9,50	7,86	7,83	5,70	8,07	6,97	1,25	54.79	
Turkey	5.58	8.96	9.46	7.83	6.00	7.21	8.54	1.38	54.96	
Algeria	5.88	8.06	8.25	7.00	6.06	7.25	9.88	1.50	53.88	
Morocco	5.00	6.63	9.25	7.88	6.00	9.00	8.25	1.13	53.14	

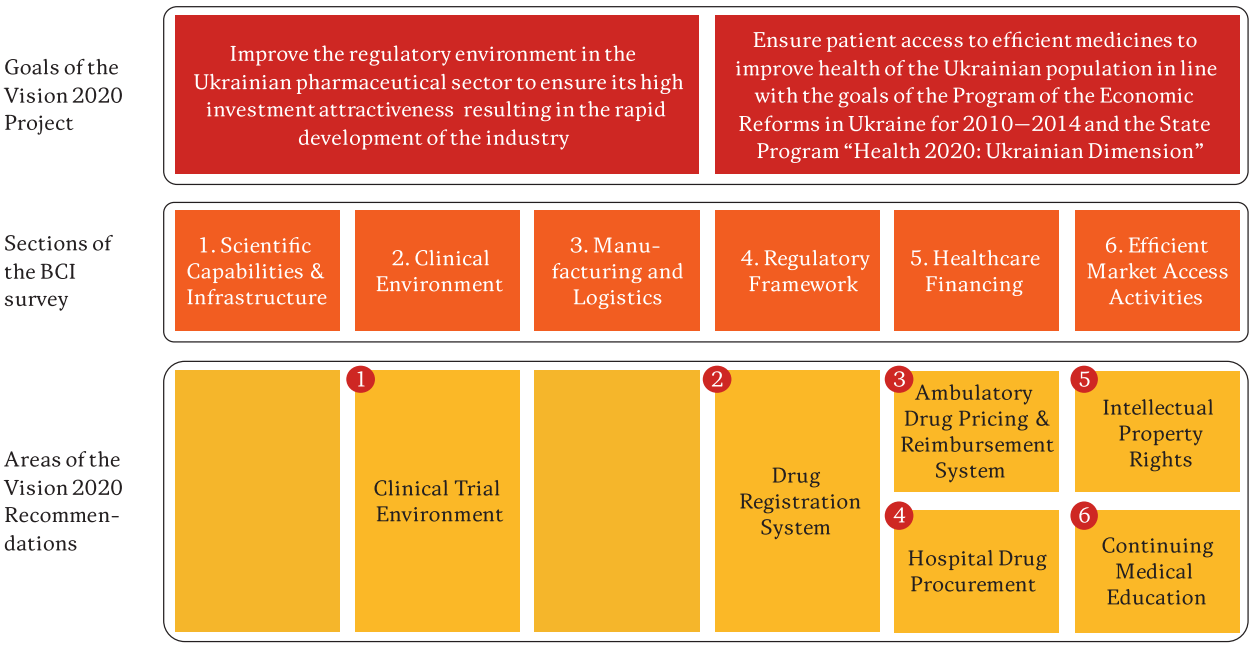
Legend: *Colours indicate*

- *— failing,*
- *— similar, or*
- *— attractive conditions in a specific category relative to other countries.*

Source: *Pugatch Consilium, PwC analysis*

Key areas for recommendations based on the BCI survey

Based on a 3-pronged approach — the BCI Survey, face-to-face interviews with industry experts and analysis of international best practises — we identified the following key areas for improvement across the value chain supporting development of the innovative healthcare and pharmaceutical industry:



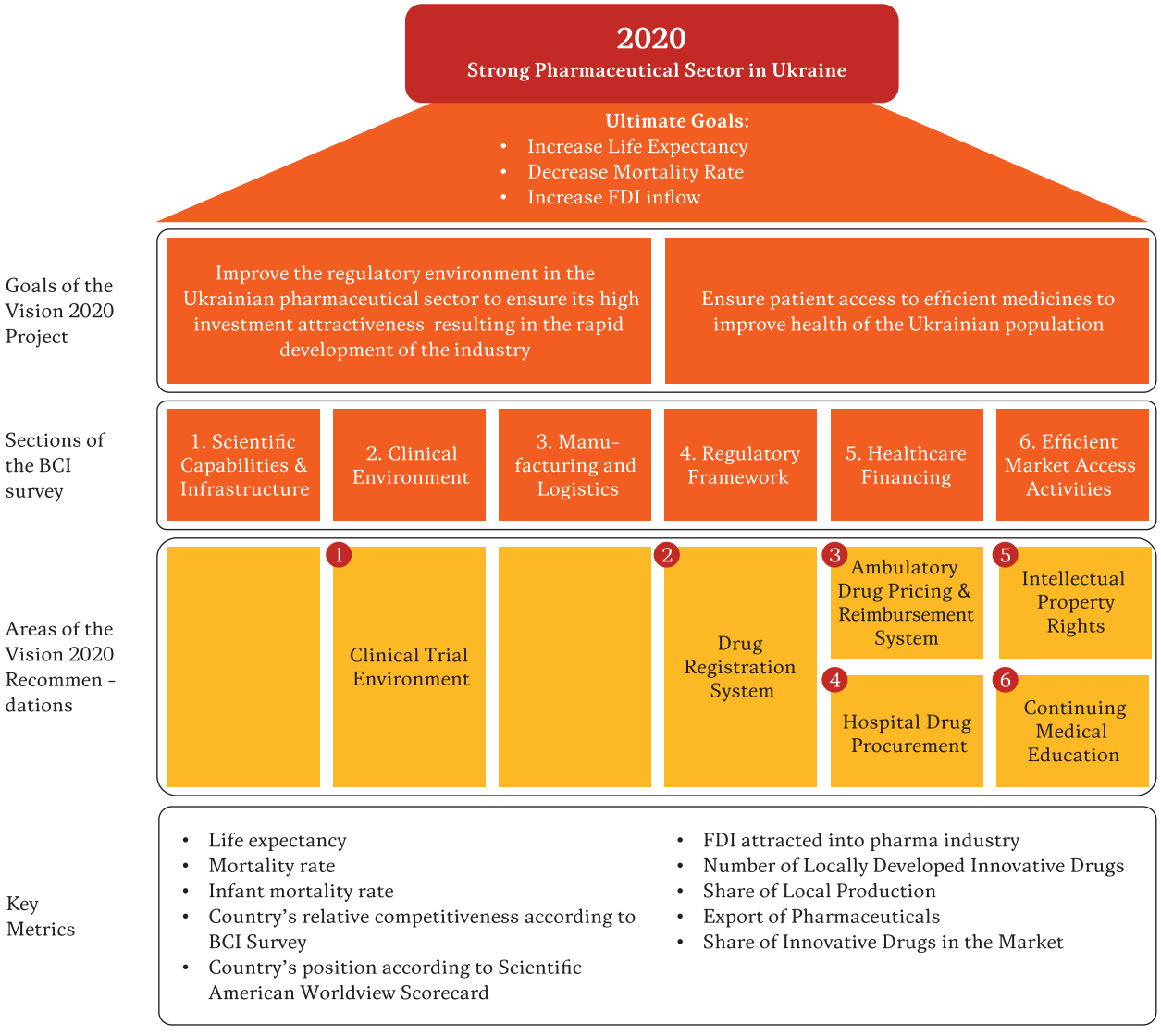
Although results of the BCI survey indicate that there is a significant room for improvement across the whole pharmaceutical value chain, these areas were identified as demonstrating the largest potential for improvement during the interviews with the industry experts based on the feasibility of required changes.

International experience (i.e. Singapore and Ireland) shows that improvement of the regulation is the first required step for attraction of the investment to the local innovative pharmaceutical sector. This step has a significant impact on the country investment attractiveness for both pharmaceutical manufacturing and clinical trials.

At the same time, development of the local scientific capabilities and infrastructure which requires extensive resources can be regarded as a long-term target that can be achieved in cooperation with the international pharmaceutical business after the strong clinical and manufacturing base is created in the country through FDI attracted.

8 POLICY RECOMMENDATIONS ON THE BASIS OF INTERNATIONAL BEST PRACTICES

Overall Project Framework



Methodology

To address issues highlighted during the interviews and BCI survey, we took a leaf out of international best practices to understand "what good looks like". We have conducted a structured in-depth analysis to understand key success factors that contribute to the high performance of best practice countries in each of the areas for improvement. We suggest ways how Ukraine can im-

prove its position and leverage its current assets and opportunities.

To develop detailed recommendations that will be based on internationally-recognized best practice, we used a 6-step approach:

1. Rationale — We identified benefits of the recommendation for Ukraine;
2. Best practice identification — We compared the current Ukraine position in terms of the development of in the area of the recommendation for which we make a recommendation vs. other countries to identify the best practice countries for further analysis;
3. Best practice analysis — We analyzed in detail the relevant policy and regulations in terms of the area of recommendation in the best practice countries vs. Ukraine
4. Key areas to address — Having compared the Ukrainian policy and regulations with internationally-recognized best practices, we identify key gaps in the area of recommendation in Ukraine based on best practice analysis and interviews with the industry experts;
5. Lessons learnt from other CEE countries — We have also analyzed experience of the comparable CEE countries in terms of development of the relevant policies and regulations to identify implications for Ukraine;
6. Implementation road map — Having the list of key gaps and implications from the experience of other CEE countries, we developed potential action steps and an implementation timeline for Ukraine.

For the purpose of this report we started each recommendation with the rationale, key areas to address and the implementation roadmap and provided the best practice analysis in the end.

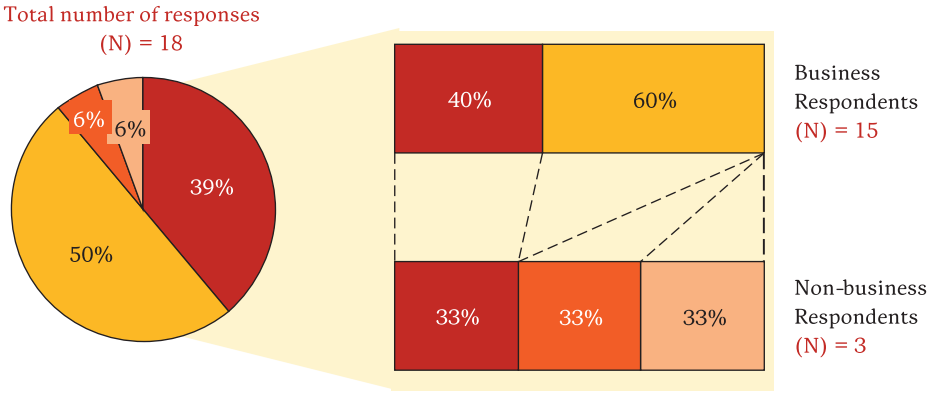
Policy dialogue

Why does policy dialogue matter?

Policy dialogue among government, industry, patients and academia on the development of the necessary regulations changes is a crucial step in developing an attractive environment to grow the local industry and improve treatment outcomes for patients. Examples of Singapore and Ireland demonstrate how transparent and consistent policy dialogue can support the rapid development of the biopharmaceutical sector providing incentives for the international pharmaceutical companies to invest in the production and R&D in a country and improvement in the demographic indicators. Development of the biopharmaceutical sector in such countries brings significant benefits both in terms of healthcare and economic growth. Singapore and Ireland demonstrate the most impressive results in this respect with the innovative pharmaceutical industry built from the scratch in the last decades.

Perception of the government-industry dialogue in Ukraine

Questions: In your view, how business-friendly is the government in your country (especially with the biopharmaceutical industry)?



Answers:

- A) Highly unsupportive of industry interests and market-based policies, at times antagonistic
- B) Somewhat unsupportive; tends towards heavy-handed policies
- C) Generally supportive with some key established relationships with industry, but political interests run contrary at times
- D) Highly supportive; long standing positive relationship and understanding with industry

Source: *Pugatch Consilium, PwC*

Best Practice Analysis

We have selected the following countries as best-practices for further comparison with Ukraine:

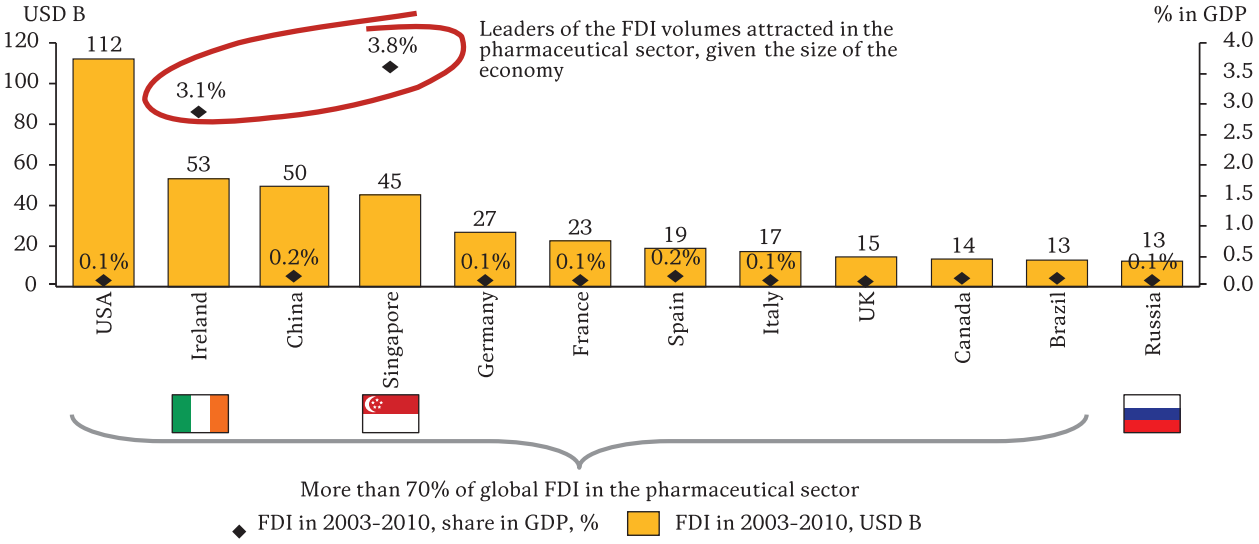
— Singapore — one of the top Asian innovative pharmaceutical markets

— Ireland — one of the top European innovative pharmaceutical markets

Facing the situation of the limited financial resources to make significant public investment into the building the local biopharmaceutical industry, Singapore and Ireland relied on the updating the country's regulation to attract FDI as one of the most efficient financial resources. The analysis below shows that these two countries are significantly higher in terms of the using FDI — these countries represent the highest share of FDI if compared to the respective GDPs.

Almost all participants believe that the current market is not achieving its potential in investments and the attraction of international investment. In their opinion, this is mainly due to the legal instability, unfavourable foreign ownership structure in addition to lack of vision and dialogue between stakeholders

Foreign direct investment (FDI) attracted in the pharmaceutical sector in 2003–2010



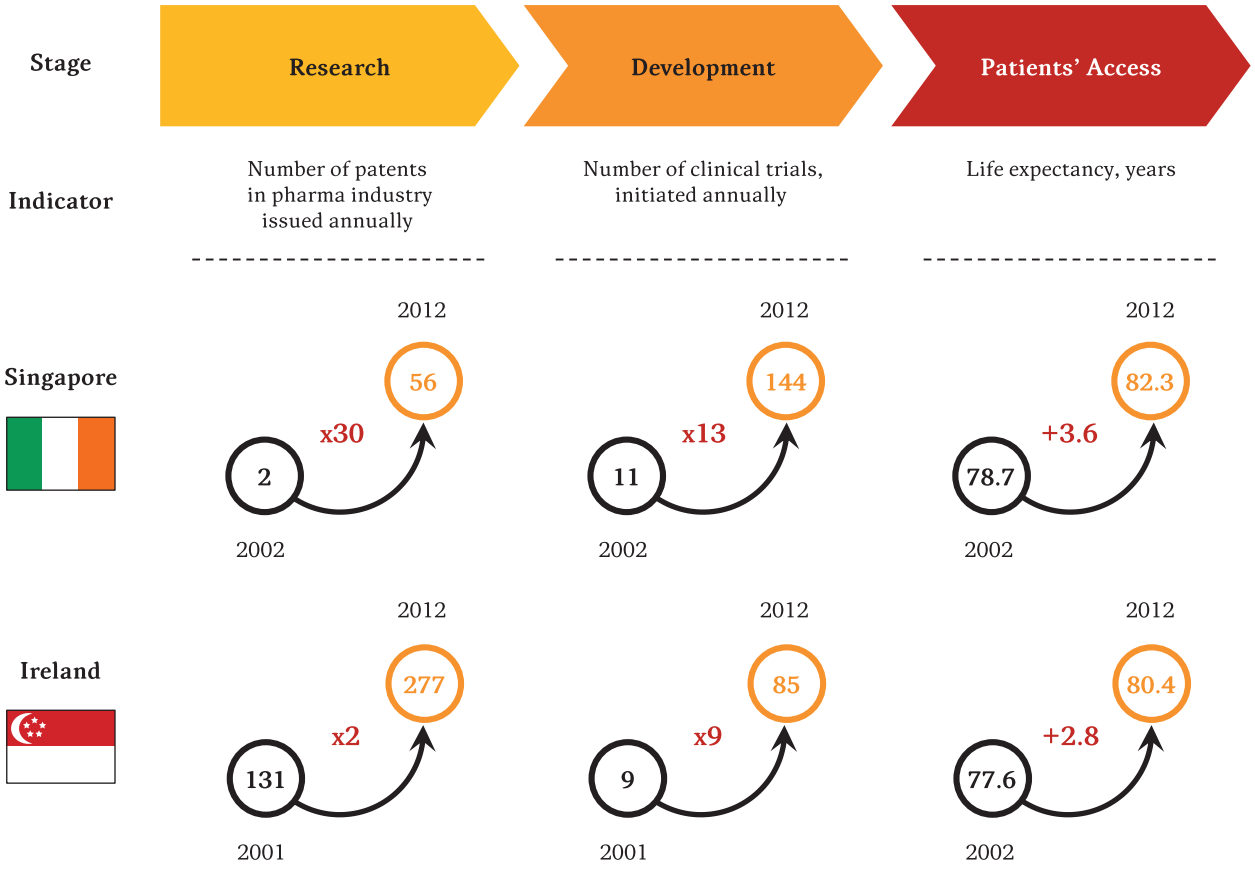
Source: *Jones Lang LaSalle; World Bank; PwC analysis*

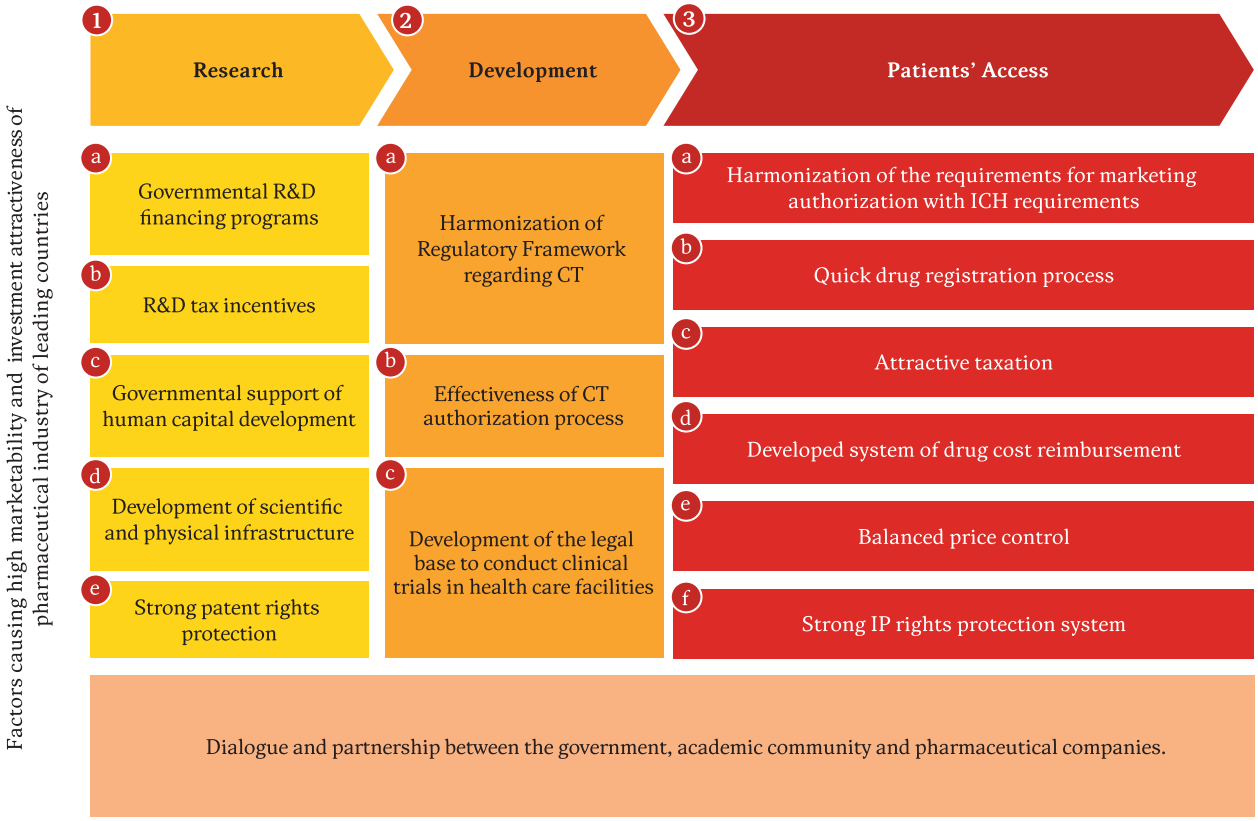
Significant investment, attracted by the pharmaceutical sector in Ireland and Singapore lead to considerable progress at all stages of the value chain — from drug development to the increase of life expectancy.

High amount of investments to pharmaceutical sector of Singapore and Ireland are determined by creation of positive regulatory environment at all stages of value chain and by close collaboration between government and business:

- Pharmaceutical research initiatives:
  - — Governmental R&D financing programs
  - — R&D tax incentives
  - — Governmental support of human capital development
  - — Development of scientific and physical infrastructure
  - — Strong patent rights protection
- Pharmaceutical development initiatives:
  - — Harmonization of Regulatory Framework regarding CT
  - — Effectiveness of CT authorization process
  - — Development of the legal base to conduct clinical trials in health care facilities
- Pharmaceutical production initiatives:
  - — Harmonization of the requirements for marketing authorization with ICH requirements
  - — Quick drug registration process
  - — Attractive taxation
  - — Scientific capabilities & infrastructure for high-quality production
- Initiatives to improve patient's access:
  - — Developed system of drug cost reimbursement
  - — Balanced price control

The building platform for the development of the necessary regulatory changes was a dialogue and partnership between the government, academic community and pharmaceutical companies.





***Source**: WIPO; clinicaltrials.gov; Business Monitor International; World Bank; PwC analysis*

We propose the following roadmap to implement effective policy dialogue in Ukraine

Element	Initiative	Initiative owners	Timeline
Government-Industry communication Platform	**Establish local communication platforms in the innovative biopharmaceutical industry** • Develop a centralized office that focuses on coordinating funding activity, education/training, and industry advocacy and is responsible for the implementation of the initiatives • Devise a collaboration forum framework where all stakeholder identify and prioritize areas for collaboration within the stakeholder groups • Develop innovative biopharmaceutical government-academia-industry boards that are responsible for advocating policy-making in the industry to promote its global competitiveness • Embed into the current regulation obligatory review of the new regulatory acts by the government-academia-industry board	MoH Industry	2014—2015
Knowledge Sharing Platform	Develop a knowledge sharing platform aimed at achieving a Knowledge Base Industry	MoH Industry	2014—2015

Clinical trial environment

Why clinical trial environment is important?

I. Attractive environment for clinical trials (CTs) drives healthcare and pharmaceutical industry in the country through:

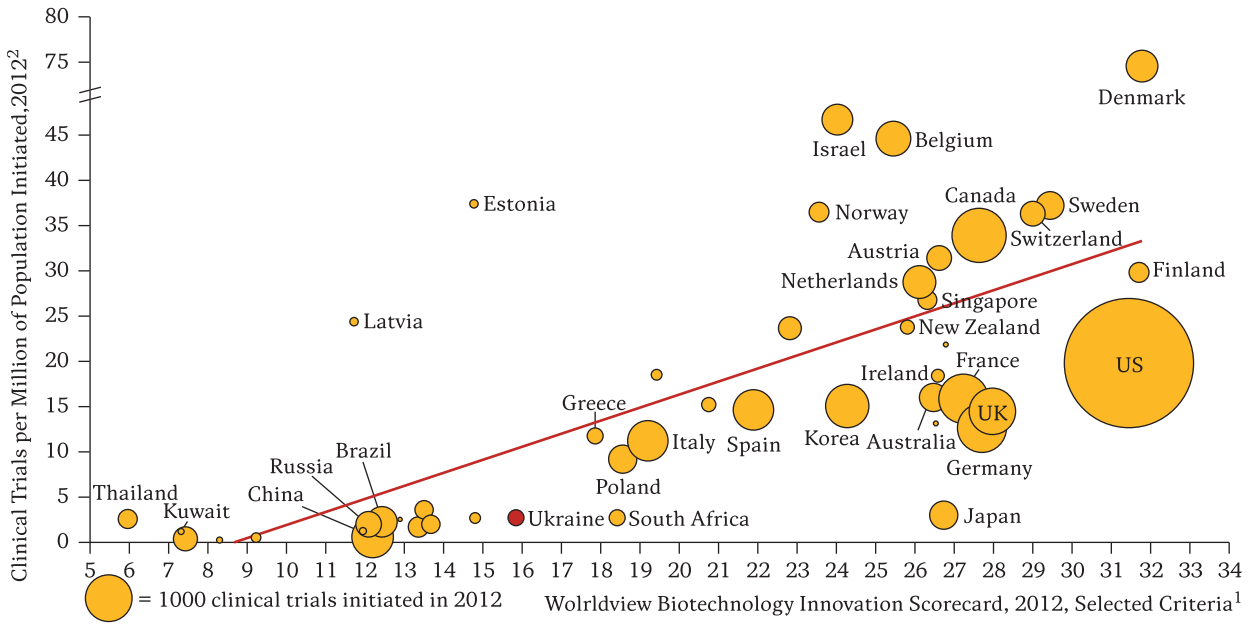
- Early patient access to the newest innovative treatments:
  - — Patients involved in clinical trials are able to receive the newest innovations during clinical trials and the course of disease
- Increased healthcare professionals' competencies:
  - — In addition to improvement in scientific capabilities and infrastructure, increase of CTs (especially international ones) leads to the improvement of healthcare professionals' competences, which results in better healthcare services provision
- Increased FDI in pharmaceuticals R&D:
  - — Attractive environment for CTs means attraction of FDI in pharmaceuticals R&D, increasing overall scientific capabilities and infrastructure in the country, which is critical for the local pharmaceutical industry development. Each year, global innovative pharmaceutical R&D spending is more than $120 billion US, and at least 60%—80% of this is invested as clinical trials

Position of Ukraine in terms of clinical trials environment

To analyze current position of Ukraine in international clinical trials, we have selected the following criteria:

1. Overall number of clinical trials initiated in 2012 — reflects overall country's involvement in international clinical trials
2. Clinical trials initiated in 2012 per capita — reflects population's involvement in international clinical trials
3. Selected criteria of the Worldview Biotechnology Innovation Scorecard — this index reflects country's readiness and attractiveness for international clinical trials

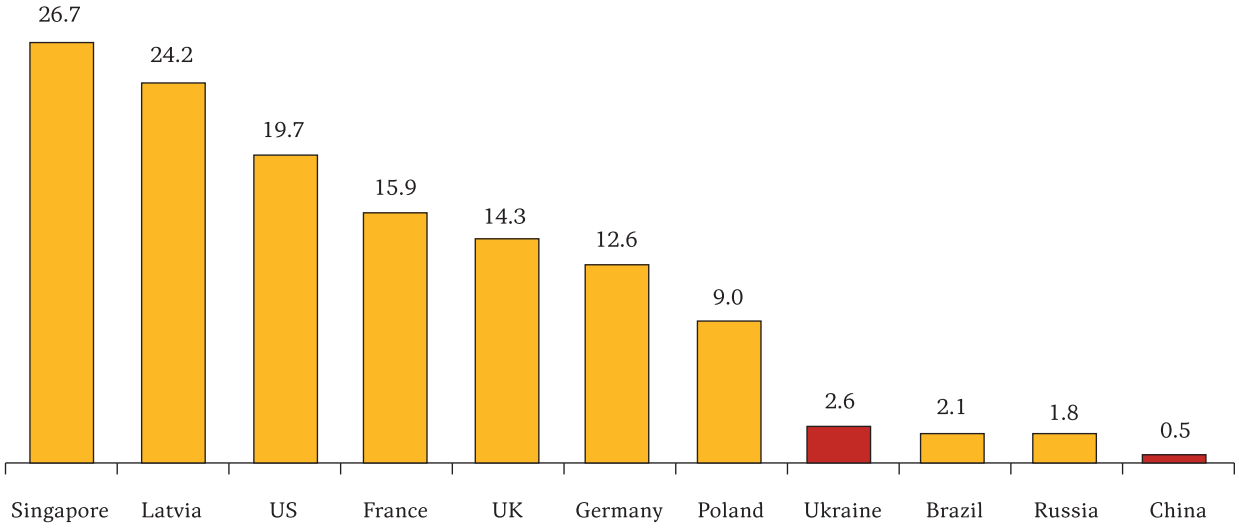
Worldview biotechnology innovation scorecard index vs. number of clinical trials initiated per capita



Source: *Scientific American World View, 2013; clinicaltrials.gov*

Note: *1) Intellectual Property, Education/Workforce, Foundations, Policy & Stability; 2) Interventional studies only are included*

Number of international interventional clinical trials initiated per million of population, 2012



Source: *clinicaltrials.gov*

According to the performed analysis, currently Ukraine lags behind developed countries both in terms of the overall number of clinical trials, number of clinical trials per capita and overall attractiveness for conduct of clinical trials. This can be explained by the poor clinical trials environment.

Based on the data represented on the chart above, we have selected the following countries as best-practices for further comparison with Ukraine:

- US, EU — top-performers in terms of overall number of clinical trials initiated
- Israel — leading non-European country in terms of initiated clinical trials per capita

Further comparison of Ukraine with the best practices in terms of clinical trials environment is provided in the Best Practice Analysis section.

Based on the comparison of Ukraine's clinical trial environment and best practice countries and the interviews with industry experts we have identified several key areas to address in the current environment. Summary of the key areas for improvement and a roadmap to address those is provided below.

Key Areas to Address in terms of clinical trials environment

Element	Key Success Factors	Key Areas to Address
1. Approval Time	1.1. Strict adherence to the duration of the application review	• No strict adherence to the deadlines — application review is often characterised by excessive delays due to the absence of mechanisms to prevent those
2. Access to Patient Populations	2.1. Good access to patient populations; Large number of naïve patients; High speed of enrolment	• Ukraine is in line with top-performing countries in terms of Access to Patient Populations
3. Access to Clinical Trials Sites	3.1. Large number of CT facilities (hospitals); Large number of highly qualified medical staff	• Complicated procedure for new CT facility enrolment — currently, in order to be enrolled in CT, a medical institution has to obtain not only licence for medical practice but also additional accreditation certificate • In some cases medical personnel involved in CTs does not have sufficient level of competences required for innovative drugs testing that can negatively affect quality of the CT results
	3.2. Clear guidelines on agreement between CTs sponsors and medical institutions	• Lack of clear guidelines on agreement between CTs sponsors and medical institutions in terms of: — Pricing of the services to be provided by the medical institution during conduct of CTs
4. Costs	4.1. Tax incentives for clinical trials (e.g. in Singapore)	• No tax incentives for CTs' sponsors, which reduces overall competitiveness of Ukraine in terms of CTs attraction
	4.2. No duties for imported clinical trials medicines	• 20% VAT and import duties for imported clinical trials medicines which results in increase of CTs' cost in Ukraine • Lack of clear guidelines on VAT evaluation by the customs. Currently the value of VAT for imported clinical trial medicines is defined by the customs that decrease the overall transparency and lead to unpredictability of the overall CTs costs
	4.3. No duties for imported equipment used in CTs	• Imported equipment used in CTs is subject to 20% VAT and import duties which results in increase of CTs cost in Ukraine

5. Other elements	5.1. Simplified procedure for Import/Export of the unregistered medical equipment to be used in CTs	• Complex and time-consuming procedure to import/export unregistered equipment for CTs • According to the current legislation, it is allowed to keep unregistered equipment in Ukraine for one year only, while some CTs may last for 3—4 years • Batch specific CoA for IMP(including comparators) should be submitted for approval • Full IMPD is required for all non-registered in Ukraine IMP • Short IMPD is required for all comparators even if these are not produced by a Sponsor of a study • RA approval is required in case of IMP expiry date extension (re-labeling) (due to IMP shelf-life prolongation • Changes to IMPD and IB updates are required of RA approval (normally — only notification to RA is required) • GMP certificates are required for all stage of IMP production (including packaging and labeling) (normally — only final QP statement is applied)

Source: *Best Practice Analysis; Interviews with Industry Experts*

We propose the following roadmap to address the identified gaps in clinical trials environment in Ukraine

Element	Initiative	Initiative owners	Timeline	Support that can be provided by pharmaceutical companies
1. Approval Time	1.1. Enforce compliance with established deadlines within current regulation a) Ensure strict adherence to the duration of application review through establishment of the relevant KPIs for the experts of MoH, State Expert Centre (SEC) and Ethical Committees (ECs) b) Develop and implement publicly available database that will contain information regarding all submitted applications, responsible experts from MoH and SEC side, and estimated deadlines of application review c) Introduce an opportunity of express review of submitted documents in some cases (for example extension of the Study, safety-related amendments, etc.) d) Introduce an opportunity of electronic submission to SEC	MoH	2014—2015	• Optional: support in development and provision of the relevant educational Programs / trainings for state experts

1. Approval Time	1.2. Enforce education of the experts attracted to examine applications (Optional) a) Develop mandatory specialized educational programs/ training for SEC experts	MoH, SEC	2016—2017	• Optional: support in development and provision of the relevant educational Programs / trainings for state experts
2. Access to Patient Populations	2.1. Increase number of CT facilities that are compliant with legislation requirements a) Improve qualifications of the medical staff involved in CTs through standardization of the educational programs focused on compliance to GCP and GLP standards and requirement b) Simplify procedure of new CT facility enrolment through cancelation of the mandatory accreditation	MoH, Industry	2014—2015	• Support in development and provision of the relevant educational Programs for medical staff • Development of the relevant draft amendments to the regulation
	2.2. Establish clear guidelines on agreement between CT sponsors and medical institutions a) Develop pricing guidelines on services to be provided by the medical institution for CTs conduction b) Introduce guidelines on allocation of payment received for conduct of CTs by medical institutions (e.g. infrastructure improvement, etc.)	MoH, Industry	2014—2015	• Support in development of the relevant guidelines
3. Costs	3.1. Introduce incentives for CT sponsors a) Introduce tax incentives for CT activities (e.g. tax credits) b) Cancel or reduce VAT and import duties for imported equipment used in CTs c) Establish clear guideline on VAT evaluation for imported CT medicines (i.e. VAT value to be calculated based on the invoice value of the imported CT products)	MoH, Ministry of Revenue and Duties of Ukraine	2016—2017	• Development of the relevant draft amendments to the regulation
4. Other Elements	4.1. Simplify procedure for obtaining permission to import/export unregistered equipment to be used in CTs a) Introduce changes to current legislation to optimize number of documents to be submitted, minimize duration of the review process, extend permission's validity according to the duration of the CTs, and provide possibility to keep equipment in Ukraine upon a CT completion	MoH	2014—2015	• Development of the relevant draft amendments to the regulation

Source: *Best Practice Analysis; Interviews with Industry Experts*

Best Practice Analysis

Element	EU	Israel	US	Ukraine
1. Approval Time	• Approval process duration — about 30 days and less; the time may be extended to 90 days for cell therapy trials • Authorisation body is able to communicate with applicant and request additional information • Overall, requirements for design of CTs is harmonized with ICH recommendations • Ethical Committees (ECs) are able to ask for additional information during review period in the number of EU countries	• Approval process duration — 30—45 ("special studies") or 60—120 days ("non-special"); most phase III studies fall into "special" category • Authorisation body does not communicate with applicant but is able to ask for additional information through EC • Requirements for design of CTs include ICH recommendations • ECs are able to ask for additional information during review period	• Approval process duration — 30 days • Authorisation body is able to communicate with applicant and request additional information • Overall, requirements for design of CTs is harmonized with ICH recommendations • ECs are able to ask for additional information during review period	• Approval process duration — about 60 days; the time may be extended for gene therapy trials • Authorisation body is able to communicate with applicant and request additional information • Overall, requirements for design of CTs are harmonized with ICH recommendations • ECs are able to ask for additional information during review period
2. Expertize and Quality	• Recognized expertise of medical staff • Strict compliance with GCP procedures			• Good quality of CTs performed by local specialists — no negative FDA inspections in recent years • Strict compliance with GCP procedures
3. Access to Patient Populations	• Good access to patient populations • Decreasing number of naïve patients • High speed of enrolment	• Limited access to patient populations due to small country population • Decreasing number of naïve patients • High speed of enrolment	• Good access to patient populations • Decreasing number of naïve patients • High speed of enrolment	• Good access to patient populations • Large number of naïve patients due to low access to • High speed of enrolment

4. Access to Clinical Trials Sites	• Over 3 hospital beds and over 3 physicians per 1000 people • Easy access to CT sites	• 3.4 hospital beds and 3.1 physicians per 1000 people • Easy access to CT sites	• 3.2 hospital beds and 2.1 physicians per 1000 people • Easy access to CT sites	• About 9 hospital beds and 4.8 physicians per 1000 people • Despite the large number of medical institutions and medical staff there is shortage of the CT facilities that are compliant with regulatory requirements
5. Costs	• High cost of CTs • No duties for imported drugs used in CTs			• Lower cost of CTs in comparison with EU and US • 20% VAT for imported drugs to be used in CTs
6. Market Potential	• Low market potential — despite large pharma market, expected marked growth is flat	• Low market potential — despite high growth rates, overall size of local pharma market is small	• Low market potential — despite large domestic pharma market, expected marked growth is flat	• High market potential — constantly growing pharmaceuticals market

Source: *1) laegemiddelstyrelsen.dk; 2) fda.gov; 3) marsdd.com; 4) gcp-academy.co.il; 4) The Order of the Ministry of Health of Ukraine as of 23.09.2009 # 690 "On Approving the procedure of conducting clinical trials of medicinal products and of evaluating the materials of clinical trials, and on Standard Statute of the Ethical Commission; 5) The Order of Ministry of Health of Ukraine as of 26.04.2011 #237 "On approval of import of unregistered medicines, reference materials, reagents in Ukraine"; 6) PwC Analysis*

Lessons learnt from the experience of the CEE countries

Of the total number of clinical trials that have been registered in Europe, CEE accounts for around a quarter — highlighting the region's importance that has grown significantly over the past decade, as many of the pharmaceutical companies as well as contract research organizations (CROs) have shifted their attention eastwards to emerging geographies, where cost is lower and patient recruitment is easier.

Within CEE region, Poland remains the largest clinical trials market and stands for roughly 20% in terms of clinical trials number in Eastern Europe. However, both patient participation and site penetration rates indicate a potential for growth.

The key drivers of the clinical trials market in Poland are the following:

Efficient patient recruitment

- Efficient patient recruitment due to the population factor, especially versus other CEE/SEE/CIS countries;
- Greater incentive for a patient to participate in clinical trial, especially versus more mature markets. Participation in clinical trials, especially in case of in-patient testing, very often provides a better quality of service, faster access to treatment (as waiting lists do not apply), the availability of expensive drugs at lower/no cost, etc.

Ensured EU standards

- Poland's accession to the EU in May 2004 eventually imposed on Poland all duties of a full Member State, including certain quality requirements of legislative framework, as well as general state administration. This accession is believed to have significant impact on the perception of Poland as a territory to conduct clinical trial.
- Additionally, Poland is expected to adopt and implement all legal requirements deriving from any amendments in the EU Directives. In alignment with this, Poland has well established, and incorporated into the clinical trials practice, ICH-GCP rules

Established know-how

- Industry feedback suggests that Poland is a respected clinical trials destination with qualified and experienced researchers and supportive medical staff
- FDA inspections show that CEE-based operators of clinical trials obtain higher results in terms of procedural transparency check than CROs in US and Western Europe

Cost advantage

- In the past, cost differentials between CEE and Western Europe were more significant than they are nowadays, both in terms of fees and operational costs. In line with overall economic development, the cost of clinical trials in CEE/SEE/CIS has been converging to Western Europe levels; however, the cost level still remains competitive

Source: *PwC analysis based on the report "Clinical trials in Poland — Key Challenges", 2010*

Implications for Ukraine

In line with other CEE countries Ukraine also has substantial and still untapped potential as a destination for clinical trials and research, thanks to large patient population, the ageing but still substantial infrastructure of Soviet-era research institutions as well as large number of medical personnel available.

Despite significant steps that have been taken by the government toward harmonization of the clinical trials legislation with EU, there are still areas for improvement, such as:

- Timing and transparency of CTs approval
- Constantly changing CT regulatory framework
- Taxation (VAT) for unregistered imported medicines and equipment to be used in CTs
- Burdensome procedure to import/export unregistered equipment for CTs

System to approve new drugs

Why efficient drug registration process is important?

I. Efficient drug registration improves patients' access to medicines resulting in improvement of overall nation's health including decrease in morbidity and mortality

- Increased medicines availability in the market

— Clear and predictable process of drug registration has a positive effect on the number of medicines available in the market (both innovative drugs and generics)

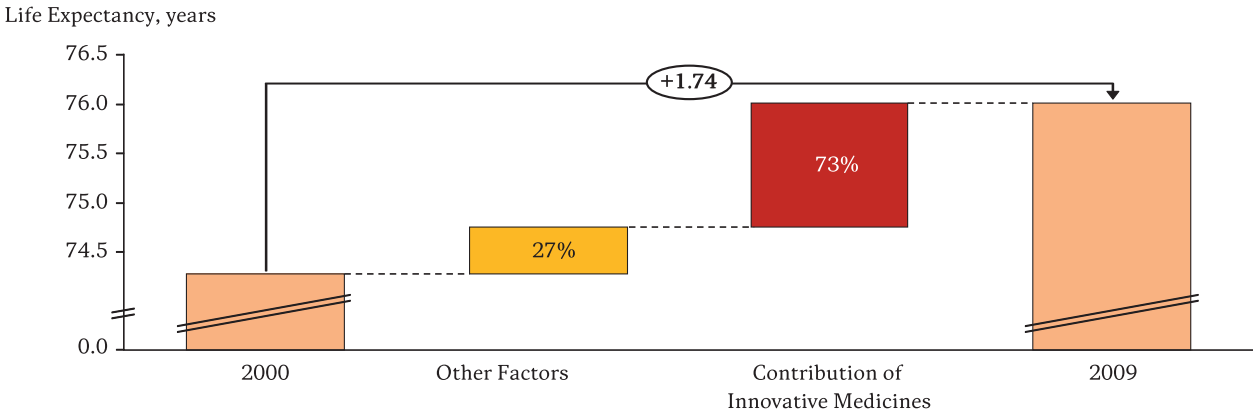
II. Attractive environment for drug registration makes a country more attractive for the pharmaceutical foreign direct investment (FDI)

- Increased volumes of the inward pharmaceutical FDI

— Countries with fast and reliable drug marketing authorization process are regarded as the primary targets for placing manufacturing and R&D facilities for production and development of new drugs by the pharmaceutical companies

Adoption of innovative medicines in the market plays a critical role in increasing a nation's life expectancy, which is confirmed by OECD countries experience:

Life Expectancy Increase in 30 OECD Countries, 2000–2009

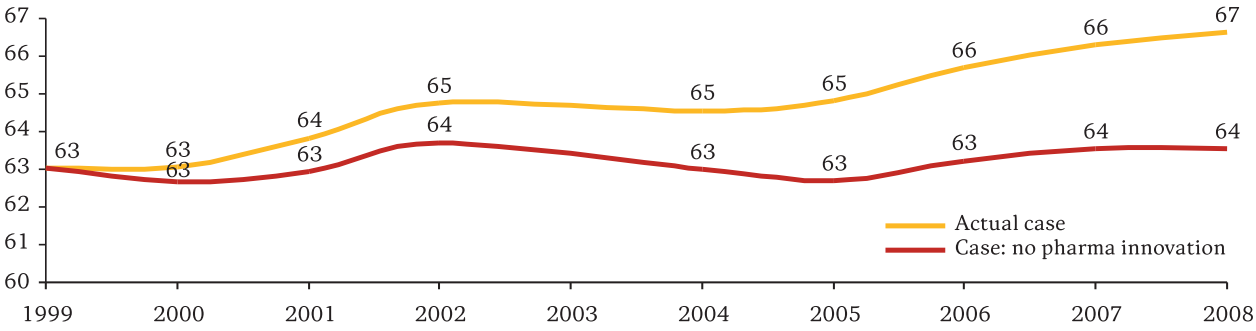


Source: *Lichtenberg F.: Pharmaceutical innovation and longevity growth in 30 developing OECD and high-income countries, 2000–2009*

As the Turkey example shows, from 1999 to 2008, mean age at death in Turkey increased by 3.6 years, from 63.0 to 66.6 years. In the absence of any pharmaceutical innovation, mean age at death would have increased by only 0.6 years. Hence, pharmaceutical innovation was estimated to have increased mean age at death in Turkey by 3.0 years during the period 1999–2008.

The estimates of the effect of pharmaceutical innovation on hospital utilization indicated that an increase in the number of molecules used to treat a disease reduces the number of hospital days due to the disease 3–4 years later. It was estimated that pharmaceutical innovation has reduced the number of hospital days by approximately 1% per year.

Comparison of the actual increase in mean age at death to the increase that would have occurred in the absence of any increase in drug vintage, years



Source: *Lichtenber, The effects of pharmaceutical innovation on mortality, hospitalization and medical expenditures in Turkey, 1999–2010*

Hospital days, 2007–2010: Actual vs. in the absence of pharmaceutical innovation

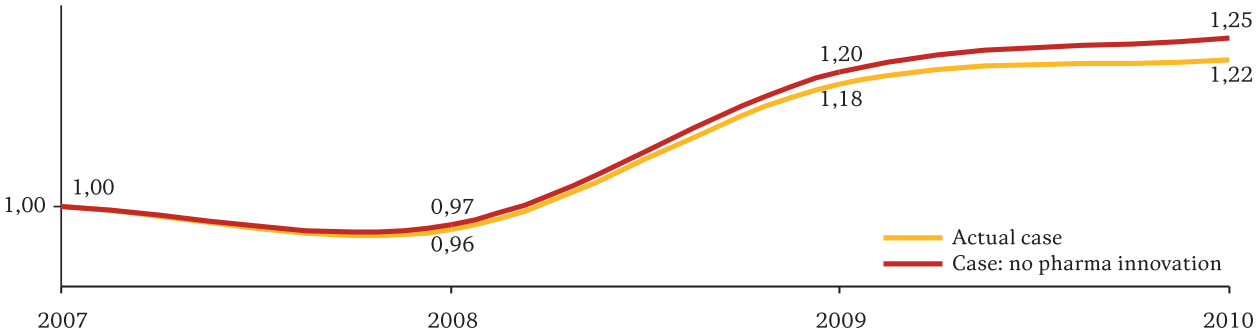


Exhibit B. Source: *Lichtenber, The effects of pharmaceutical innovation on mortality, hospitalization and medical expenditures in Turkey, 1999–2010*

The estimates of the effect of pharmaceutical innovation on age at death, hospital utilization and pharmaceutical expenditure to assess the incremental cost-effectiveness of pharmaceutical innovation, i.e., the cost per life-year gained from the introduction of new drugs shows that the cost per life-year gained from pharmaceutical innovation is $2,813. The results indicate that innovative drugs are highly cost effective options for the Turkish health care system. Apart from their invaluable contribution to longevity, this contribution is also value for money.

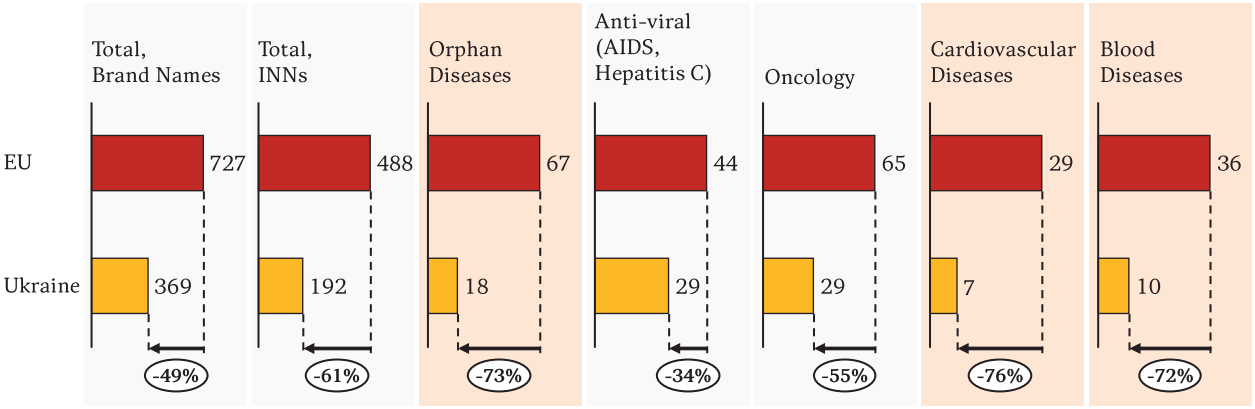
Estimation of Incremental cost-effectiveness of pharmaceutical innovation in Turkey, 1999—2008

	Life expectancy (mean age at death)	Annual per capita health expend (USD)	Lifetime per capita health expend (USD)	ICER (USD)
Actual value in 2008	67.1	906	60,798	2,813
Estimated value in 2008 in the absence of the 9 previous years of pharmaceutical innovation	64.1a	818b	52,471	
Difference	3.0	88	8,327	

Source: *Lichtenber, The effects of pharmaceutical innovation on mortality, hospitalization and medical expenditures in Turkey, 1999—2010*

Ukraine's position compared to other countries in terms of efficiency of drug approval process

Number of Drugs Registered in Ukraine and EU, total and by therapeutic area



Source: *State Administration of Ukraine on Medicinal Products*

As demonstrated by the chart above, the number of new drugs authorized in Ukraine is far below than in the EU. The gap is especially serious in the areas of orphan diseases and cardiovascular and blood diseases. This results in the limited patient access to the efficient treatment and underperformance of the overall healthcare system.

Although Ukraine made significant step towards the harmonization of the drug registration process with EU there are still several areas to address (please see below).

To identify these areas we compared the drug registration system of Ukraine to that of the following countries:

- US and EU — top pharmaceutical markets adopting the largest number of innovative medicines annually
- Germany — the largest EU innovative medicines approver

Comparison of Ukraine drug registration system with that of the selected countries is provided in the Best Practice Analysis section.

Key Areas to Address in terms of the Drug registration process

	Key Success Factors	Key Areas to Address
1. General requirements	1.1. Evaluation of drug quality and safety is performed through manufacturer's adherence to the Pharmacopeia, GMP certification and dossier examination	• Despite Ukraine's membership in the PIC/S[1)], according to the recently amended legislation, companies are required to file a document that confirms compliance with GMP in Ukraine issued by the State Administration on Medicinal Products (SAMP)
	1.2. Strict adherence to the duration of application review and procedures	• No strict adherence to the deadlines — registration process is often characterised by excessive delays. Sometimes duration of application review might be extended to 1 year or longer due to various bureaucratic issues[2)]
2. Validity of marketing authorizations	2.1. After one renewal, the marketing authorization shall remain valid for an unlimited period, unless the competent regulatory authority decides otherwise	• Currently, one should apply for renewal of the marketing authorization every 5 years to prove that quality, efficacy and safety characteristics are maintained and the risk-benefit ratio of the medicinal product is still favourable
3. Drugs for certain diseases and innovative medicines	3.1. Specialized (accelerated) procedure for marketing authorization of drugs for certain diseases and innovative medicines	• There is no accelerated procedure for market authorization of innovative medicines
4. Biosimilars	4.1. Specialized procedures for marketing authorization of biosimilars — specialized biosimilarity tests are required	• Lack of clear requirements to and guidelines on: — Pre-clinical and clinical data to be submitted by the applicant — Risk management plan to be submitted by the applicant

Note: *1) Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme;*
2) Based on the industry expert interviews

We propose the following roadmap to address the identified gaps in the drug approval process in Ukraine

Element	Initiative	Initiative owners	Timeline	Support that can be provided by pharmaceutical companies
1. General requirements	1.1. Introduce recognition of GMP certificate issued by PIC/S1) members without any further confirmation by local authorities required	MoH, SAMP2), SEC3)	2014—2015	• Development of the relevant draft amendments to the regulation

1. General requirements	1.2. Enforce compliance with established deadlines within current regulation a) Ensure strict adherence to the duration of authorization procedure through establishment of the relevant KPIs for the experts involved in dossier examination b) Introduce specialized trainings for the experts involved in assessment of the application dossier to ensure familiarization with current registration procedures and regulations thus minimize risk of further confusions and delays during the drug approval process c) Increase operating efficiency of the authorization bodies through organizational structure and internal processes improvement	MoH, SEC, Industry	2016—2017	• Support in the development and provision of the specialized trainings for experts involved in assessment of the application dossier
2. Validity of marketing authorizations	2.1. Extend validity of the marketing authorization upon first renewal — after one renewal, the marketing authorization shall remain valid for an unlimited period, unless the competent regulatory authority decides otherwise	MoH, SEC	2014—2015	• Development of the relevant draft amendments to the regulation
3. Innovative drugs	3.1. Introduce accelerated procedure (90 days) of marketing authorization for innovative medicines that have been already registered according to the centralized EU procedure	MoH, SEC	2014—2015	• Development of the relevant draft amendments to the regulation
4. Biosimilars	4.1. Further development of the requirements to and guidelines on biosimilars evaluation a) Develop clear requirements to and guidelines on pre-clinical and clinical information to be submitted by the applicant for biosimilars registration b) Develop clear requirements to and guidelines on the risk management plan to be submitted by the applicant for a biosimilar registration	MoH, SEC	2014—2015	• Support in development of the requirements to and guidelines to biosimilars evaluation based on the EU practice

Note: *1) Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme; 2) State Administration on Medicinal Products; 3) State Expert Centre*

Best Practice Analysis

Element	International Examples			Ukraine
	US	EU (centralized)[1]	Germany	
1. General requirements	• Pre-application meetings are available • Authorization bodies are able to request additional information during dossier review • In case of additional questions, clock stops on timetable • Evaluation of drug quality and safety is performed through manufacturer's adherence to the Pharmacopeia (not applicable to new innovative pharma), GMP certification and dossier examination • Registration dossier is prepared in line with Common Technical Document (CTD)2, reflecting requirements for pre-clinical, clinical studies, quality and efficiency developed by ICH3 and adopted by US, EU and Japan			• Pre-application (free of charge) meetings are available • Authorization bodies are able to request additional information during dossier review (once during preliminary expertise and twice during specialized expertise of the dossier materials) • In case of additional questions, clock stops on timetable • Quality evaluation is performed through manufacturer's adherence to the National Pharmacopeia or in case of unavailability of information to other leading Pharmacopeia (EU, Germany, United States, Japan, United Kingdom, etc.), GMP certification and dossier examination • Despite Ukraine's membership in the PIC/S, according to the recently amended legislation, companies are required to file a document that confirms compliance with GMP in Ukraine issued by the SAMP • Requirements for dossier preparation (as well as technical requirements for pre-clinical and clinical studies) are in line with CTD
2. Validity of marketing authorizations	• In most countries, a marketing authorization is valid for a period of 5 years. After this period, one should apply for renewal of the marketing authorization, usually by providing minimal data proving that quality, efficacy and safety characteristics are maintained and the risk-benefit ratio of the medicinal product is still favourable • After one renewal, the marketing authorization shall remain valid for an unlimited			• Currently a marketing authorization is valid for a period of 5 years • Every 5 years, one should apply for renewal of the marketing authorization

3. Drugs for certain diseases and innovative medicines	• Specialized (accelerated) procedure for marketing authorization of drugs for certain diseases and innovative medicines — 180 calendar days for innovative drugs vs. 300 calendar days for non-innovative drugs • Overall the amount of data needed to authorize orphan drug is less than for other drugs	• Centralized procedure of drug registration (minimum 210 calendar days) for a wide range of innovative medicines and orphan drugs — this speeds us the access of innovative medicines to the whole EU market • Overall the amount of data needed to authorize orphan drug is less than for other drugs	• Innovative medicines and orphan medicines are not authorized by German authority — centralized EU procedure is used	• Specialized (accelerated) procedure for marketing authorization of drugs for certain diseases (e.g. tuberculosis, HIV/AIDS, hepatitis, orphan diseases) — 90 working days vs. 210 working days in case of standard procedure • Accelerated procedure is applicable in following cases: — Original drug has been registered by FDA, EMA1, Swissmedic2, PMDA3, MHRA4 or TGA5 — Drugs and manufacturing facility have been prequalified by WHO • Under accelerated procedure, dossier examination of drugs for certain diseases is conducted out of turn and free of charge
4. Biosimilars	• Requirements and guidance for biosimilars registration are still under development (draft guidelines are developed by FDA) • Accelerated procedure for marketing authorization — 180 calendar days for biosimilar vs. 300 calendar days for non-innovative and generic drugs	• Developed clear requirements to and guidelines on biosimilars registration: — Drug quality control — Pre-clinical and clinical data to be submitted — Risk management plan to be provided • Specialized requirements to and guidelines on different types of biosimilars registration • Overall, the amount of data needed to authorize biosimilar is less than for original biopharmaceutical drug only for EU • No accelerated procedure	• Biosimilars are not authorized by German authority — centralized EU procedure is used	• Guidelines on biosimilar registration in terms of drug quality control are harmonized with EU • Lack of clear requirements to and guidelines on: — Pre-clinical and clinical data to be submitted by the applicant — Risk management plan to be submitted by the applicant • No accelerated procedures

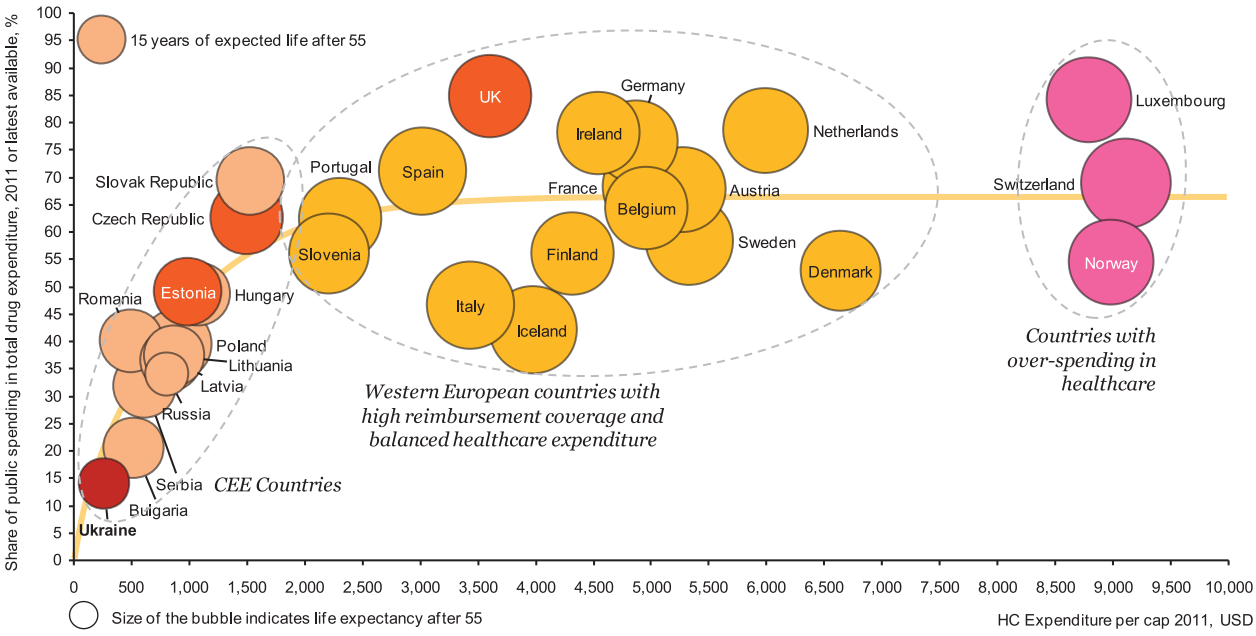
Source: *FDA; EMA; Federal Association of Pharmaceutical Manufacturer of Germany; The Order of Ministry of Health of Ukraine of 04.01.2013 N 3 "On examination of the medicines' dossier materials submitted for the state registration (re-registration) as well as on examination of changes introduced to the dossier materials during validity of the registration certificate"; PwC Analysis*

Note: *1) EMA — European Medicines Agency; 2) Swissmedic — Swiss Agency for Therapeutic Products ; 3) PMDA — Pharmaceuticals and Medical Devices Agency, Japan; 4) MHRA — Medicines and Healthcare Products Regulatory Agency, UK ; 5) TGA — Therapeutic Goods Administration, Australia*

Public drug provision

Position of Ukraine in terms of public drug provision

Healthcare Expenditure vs. Share of Public Drug Provision and Life Expectancy



***Source**: World Health Organization (Europe); World Bank; PwC analysis*

While increase in coverage of the public drug provision naturally requires higher public spending, several European countries, e.g. UK, demonstrate high coverage of population by public drug provision with the level of health expenditure significantly below peers. Countries with low coverage of the public drug provision and low health expenditure tend to have lower life expectancy. Several countries, e.g. Norway, have high health expenditure, while maintaining the same or lower coverage of population by the public drug provision and life expectancy compared to other developed countries, which may indicate inefficiency of the drug reimbursement system and public drug procurement.

Ukraine lags behind developed countries in terms of the coverage of population by the public drug provision and has lower life expectancy than countries of the Central and Eastern Europe with the comparable level of the healthcare expenditure, e.g. Romania. Among other factors, this is explained by the lack of the universal drug reimbursement system.

To develop recommendations for development of the drug provision system we analyzed the systems of the following countries:

- UK — international best practice example based on the balance of the drug reimbursement coverage and healthcare expenditure
- Czech Republic — CEE top-performing country in terms of life expectancy and drug reimbursement coverage (the system of Slovak Republic was not considered due to lower life expectancy and due to its principal similarity to the system of Czech Republic)
- Estonia — the third CEE top-performing country in terms of life expectancy and drug reimbursement coverage (the system is different from that of Czech Republic in a number of aspects)

The analysis of the public drug provision systems of these countries is provided in the relevant best practice analysis sections.

Ambulatory drug reimbursement system

Why does reimbursement system matter?

I. Comprehensive reimbursement system increases welfare of a country

- Increase in economic productivity through increase in life expectancy
  - Patient access to drugs has significant impact on life expectancy and health indicators through improvement in treatment of diseases, which in turn drives economic growth
- Prevention of higher costs in later stage treatment

— Patient access to drugs on the stage of ambulatory treatment decreases incidence of later stage complications, and hospitalization frequency :thus cuts costs in the in-patient care

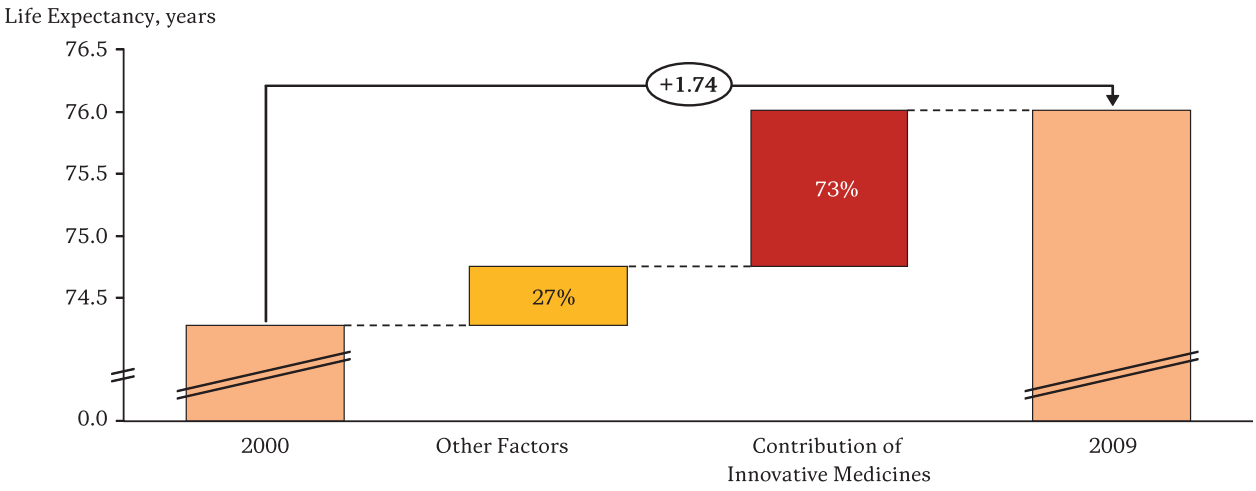
- Improvement in quality of life
  — Patient access to drugs is one of the most important social targets of the state as it improves health and quality of life of its citizens

II. Improvement of patient access to drugs is in line with the Ukrainian government targets

- To ensure availability of high-quality, effective and safe drugs to meet the needs of the population is one of the key initiative under Government Program of Economic Reforms of Healthcare for 2010—2014

Provision of innovative medicines to the patients plays a critical role in increasing a nation's life expectancy, which is confirmed by OECD countries experience:

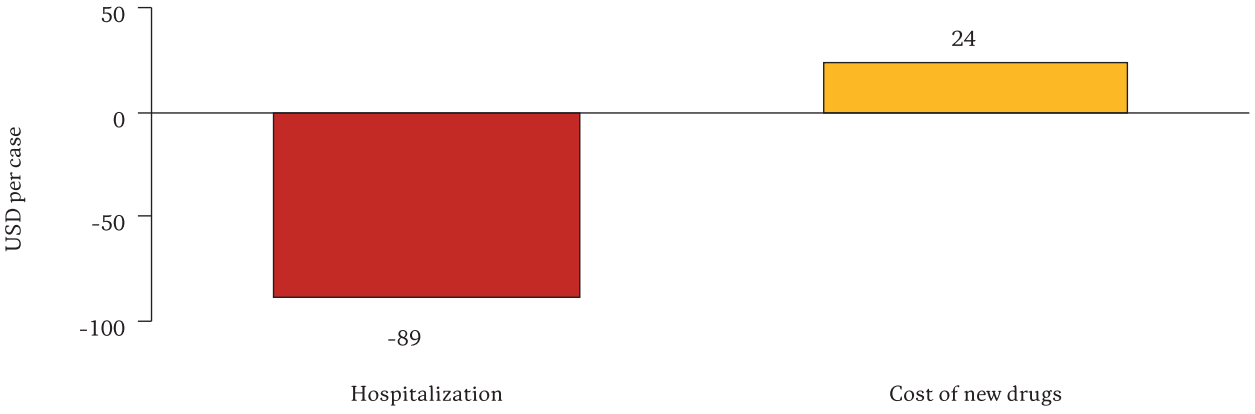
Life Expectancy Increase in 30 OECD Countries, 2000—2009



Source: *Lichtenberg F.: Pharmaceutical innovation and longevity growth in 30 developing OECD and high-income countries, 2000—2009*

In addition access to the modern medication leads to reduction of healthcare costs through prevention of the avoidable hospitalizations, which is illustrated by the international example below.

Cost of newer cardiovascular drugs compared to savings in hospitalization in 20 OECD countries, 1995—2003

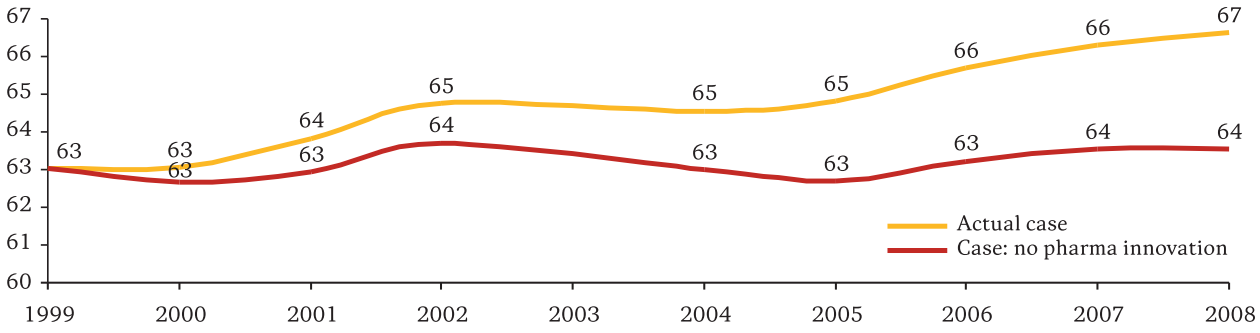


Source: *Lichtenberg FR (2009) Have newer cardiovascular drugs reduced hospitalization? Evidence from longitudinal country-level data on 20 OECD countries, 1995—2003.*

As the Turkey example shows, from 1999 to 2008, mean age at death in Turkey increased by 3.6 years, from 63.0 to 66.6 years. In the absence of any pharmaceutical innovation, mean age at death would have increased by only 0.6 years. Hence, pharmaceutical innovation was estimated to have increased mean age at death in Turkey by 3.0 years during the period 1999—2008.

The estimates of the effect of pharmaceutical innovation on hospital utilization indicated that an increase in the number of molecules used to treat a disease reduces the number of hospital days due to the disease 3—4 years later. It was estimated that pharmaceutical innovation has reduced the number of hospital days by approximately 1% per year.

Comparison of the actual increase in mean age at death to the increase that would have occurred in the absence of any increase in drug vintage, years



Source: *Lichtenber, The effects of pharmaceutical innovation on mortality, hospitalization and medical expenditures in Turkey, 1999–2010*

Hospital days, 2007–2010: Actual vs. in the absence of pharmaceutical innovation

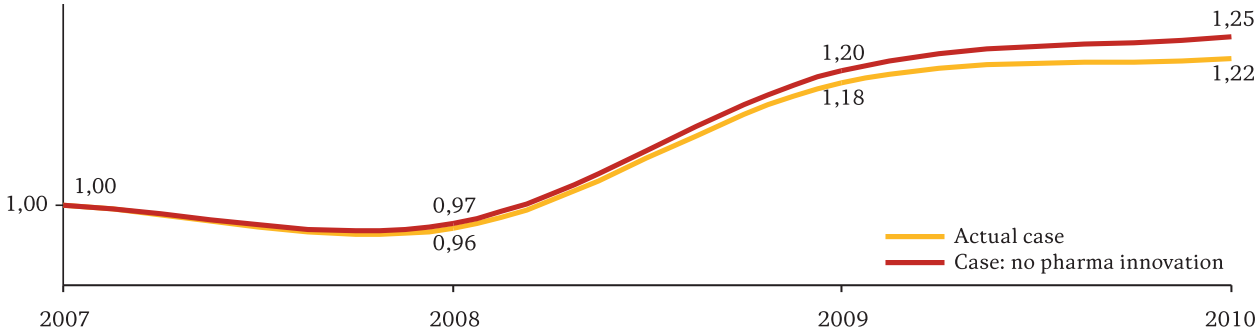


Exhibit C. Source: *Lichtenber, The effects of pharmaceutical innovation on mortality, hospitalization and medical expenditures in Turkey, 1999–2010*

The estimates of the effect of pharmaceutical innovation on age at death, hospital utilization and pharmaceutical expenditure to assess the incremental cost-effectiveness of pharmaceutical innovation, i.e., the cost per life-year gained from the introduction of new drugs shows that the cost per life-year gained from pharmaceutical innovation is $2,813. The results indicate that innovative drugs are highly cost effective options for the Turkish health care system. Apart from their invaluable contribution to longevity, this contribution is also value for money.

Estimation of Incremental cost-effectiveness of pharmaceutical innovation in Turkey, 1999–2008

	Life expectancy (mean age at death)	Annual per capita health expend (USD)	Lifetime per capita health expend (USD)	ICER (USD)
Actual value in 2008	67.1	906	60,798	2,813
Estimated value in 2008 in the absence of the 9 previous years of pharmaceutical innovation	64.1a	818b	52,471	
Difference	3.0	88	8,327	

Source: *Lichtenber, The effects of pharmaceutical innovation on mortality, hospitalization and medical expenditures in Turkey, 1999–2010*

Current state of the ambulatory drug reimbursement system in Ukraine

Ukraine does not have a universal ambulatory drug reimbursement system at the moment. However, several government programs are supposed to provide free access to required medicines.

These programs include:

- Pilot project of the drug reimbursement and pricing system for hypertension disease treatment (hereafter Anti-hypertension Pilot Project)
- National Programs on certain diseases:
  - — National Program for Cancer Prevention and Treatment in 2007—2016
  - — National Program "Diabetes mellitus" in 2009—2013
  - — National Program for HIV prevention, treatment, care and support for people suffering from HIV and AIDS for 2009—2013 State Program for prevention and treatment of cardio-vascular diseases

In addition, the Order of the Cabinet of Ministers of Ukraine as of 17 August 1998 #1303 defines the social groups, which are subject to free drug provision (including veterans, Chernobyl victims, pensioners, children under 3 years old, disabled children under 16 years old, and some other) and social groups that are subject to 50% reimbursement of drug costs (including disabled, children between 3 and 6 years old and honorary donors).

The Order also defines the 35 conditions, ambulatory treatment of which must involve free drug provision (e.g. oncology, HIV/AIDS, Tuberculosis, Diabetes, Rheumatoid Arthritis, etc.).

The analysis of the coverage of the 20 disease most critical for Ukraine by the drug reimbursement according to the existing regulations is provided below.

Top 20 Diseases Causing Deaths in Ukraine (2011) vs. Existing Regulations that Imply Ambulatory Drug Reimbursement

Disease	Share of Deaths Caused by the Disease in the Total number of Deaths in Ukraine, 2012	Is Public Provision of the Ambulatory Drugs for the Disease Implied by Current Regulation?	Regulations that Introduced Drug Reimbursement for the Disease
1. Coronary Heart Disease	49.4%	Yes	Partially covered under the Anti-hypertension Pilot Project
2. Stroke	15.4%	Yes	Order of the Cabinet of Ministers of Ukraine #1303
3. HIV/AIDS	3.5%	Yes	National Program for HIV prevention, treatment, care and support for people suffering from HIV and AIDS for 2009—2013 Order of the Cabinet of Ministers of Ukraine #1303
4. Liver Disease (excl. cancer)	3.5%	No	—
5. Lung Cancer	2.1%	Yes	National Program for Cancer Prevention and Treatment in 2007—2016 Order of the Cabinet of Ministers of Ukraine #1303
6. Colon-Rectum Cancer	1.9%	Yes	
7. Lung Disease (excl. cancer, TB and Asthma)	1.9%	No	—
8. Tuberculosis	1.8%	Yes	Order of the Cabinet of Ministers of Ukraine #1303

9. Stomach Cancer	1.6%	Yes	National Program for Cancer Prevention and Treatment in 2007—2016 Order of the Cabinet of Ministers of Ukraine #1303
10. Breast Cancer	1.3%	Yes	
11. Inflammatory Heart Disease	1.0%	No	—
12. Pancreas Cancer	0.6%	Yes	National Program for Cancer Prevention and Treatment in 2007—2016 Order of the Cabinet of Ministers of Ukraine #1303
13. Oral Cancer	0.5%	Yes	
14. Prostate Cancer	0.5%	Yes	
15. Leukemia	0.4%	Yes	
16. Bladder Cancer	0.4%	Yes	
17. Diabetes Mellitus	0.4%	Yes	National Program "Diabetes mellitus» in 2009—2013 Order of the Cabinet of Ministers of Ukraine #1303
18. Ovary Cancer	0.4%	Yes	National Program for Cancer Prevention and Treatment in 2007—2016 Order of the Cabinet of Ministers of Ukraine #1303
19. Uterine Cancer	0.3%	Yes	
20. Cervical Cancer	0.3%	Yes	

Source: *WorldLifeExpectancy Project; PwC analysis*

Although the existing regulations introduce drug reimbursement for diseases causing over 80% of deaths in Ukraine, in practice the patients struggle to receive necessary medication which is a result of underfinancing as well as the several key issues in the overall reimbursement system (please see below).

Key Areas to Address in terms of the Ambulatory Drug Reimbursement

Element	Key Success Factors	Key Areas to Address
1. Population Coverage	1. a) Universal coverage for all citizens of country	• Reimbursement coverage is limited to benefit-entitled social groups and people suffering from certain diseases • Insufficient financing to provide free access to medicines for the people who are subject to ambulatory drug reimbursement according to the current regulations — de facto, no free access is provided for most of the patients
2. Drug Coverage	2. a) Universal drug coverage, or Regularly updated unified positive list with innovative drugs included into it based on applications from drug manufacturers reviewed during the health technology assessment process	• No unified reimbursement list — several lists exist; the lists are used for price regulation and hospital procurement

3. Cost-Benefit Assessment of Drugs	3. a) Dedicated body to conduct assessment (HTA based approach) 3. b) Established assessment procedure aligned with EU 3. c) Assessment results are used to support decision on reimbursement	• No dedicated body to conduct drug assessment: assessment is currently conducted by a special committee of the Ministry of Health as a part of Essential Drug List review • No established assessment procedure • Pricing decisions are not linked to assessment results
4. Prescription Guidelines	4. a) Prescription based on clinical guidelines 4. b) No interchangeability for biosimilars and drugs with the narrow therapeutic index	• Clinical guidelines are under development • Insufficient control over adherence to the prescribed treatment • INN prescription is mandatory except for biosimilars, reimbursed drugs and drugs provided to a patient free of charge or with a discount and drugs that are subject to item recording (psychotropic and narcotic drugs)
5. Drug Price Regulation	5. a) Separate procedures for regulation of prices of generics/biosimilars and patented drugs 5. b) Pricing of innovative drugs based on the international reference pricing with the principle of recognition of value of innovative drugs 5. c) Regular review of prices (either increase or decrease) to ensure commercial sustainability of drug production and cost-efficiency of the drug provision 5. e) System of regressive wholesale and retail mark-ups	• The drug pricing procedures are not developed and are universal for patented, generic and biosimilar drugs • Complicated system of external and internal reference pricing under the Anti-hypertension Pilot Project
6. Financing	6. a) Differentiated co-payment schemes to limit public expenses, but ensure access to drugs for vulnerable social groups	• Overall insufficient financing of the drug reimbursement system • Lack of the mandatory health insurance system to provide a financial base for a drug reimbursement system • No co-payment schemes (except for 50% discount on drugs for certain social groups and co-payment introduced under the Anti-hypertension Pilot Project)
7. Drug Procurement and Dispensing	7. a) No centralized procurement the ambulatory drugs with the reimbursement mechanism used instead	• Inaccurate demand planning and cases of inappropriate tendering procedures within the centralized procurement of ambulatory drugs lead to further drug shortages in regions

We Propose the Following Roadmap to Develop the Reimbursement System in Ukraine

Element	Initiative	Initiative owners	Timeline	Support that can be provided by pharmaceutical companies
Coordination of the Overall System Development	Establish a Joint Task Force to manage the drug reimbursement system development Establish a Joint Task Force on the drug reimbursement system development under MoH including representatives from: • Government • Academia • Patient organizations • Medical societies • Pharmaceutical industry	MoH	2014–2015	• Participation in the Joint Task Force on the development of the drug reimbursement system
1. Population Coverage	1.1. Enforce the financing of the ambulatory drug provision programs provided by the current regulation through introduction of new ambulatory drug reimbursement projects			• Support in the development of the relevant regulations • Support in planning costs of the drug reimbursement projects
	a) Expand current Anti-hypertension Pilot Project to cover people with the coronary heart disease — the most critical disease for Ukraine (start with Myocardial infraction as the biggest cause of death in CHD) b) Consider introduction of the full ambulatory drug reimbursement coverage for certain social groups (e.g. neonates)	MoH Joint Task Force	2014–2015	
	c) Launch projects to provide ambulatory drug reimbursement (similar to the Anti-hypertension Pilot Project) for 10 most critical diseases that are included into the Order of the Cabinet of Ministers of Ukraine #1303 d) Allocate the priority target budgets for implementation of the reimbursement projects based on the disease prevalence	MoH Joint Task Force	2014–2017	
	e) Launch projects to provide ambulatory drug reimbursement (similar to the Anti-hypertension Pilot Project) for all 35 diseases that are included into the Order of the Cabinet of Ministers of Ukraine #1303 f) Allocate target budgets for implementation of the reimbursement projects based on the disease prevalence	MoH Joint Task Force	2018–2020	

2. Drug Coverage	2.1. Expand the drug coverage under existing and new drug reimbursement projects			
	a) Introduce a procedure for drug manufacturers to apply for inclusion into the drug reimbursement lists under the pilot projects based on the latest clinical guidelines and assessment by an independent body	MoH Joint Task Force	2014—2015	• Support in development of a procedure for drugs manufacturers to apply for inclusion into the drug reimbursement lists • Development of the relevant draft regulations
	b) Expand the range of drugs reimbursed under the Anti-hypertension Pilot Project to include new drugs in line with the latest clinical guidelines and to cover drugs for treatment of the coronary heart disease		2014—2020	
	c) Introduce and regularly update drug reimbursement lists for ambulatory drug reimbursement projects being launched		2014—2020	
3. Prescription Policies	3.1. Ensure efficient ambulatory drug prescription under the pilot projects in line with the latest clinical guidelines a) Ensure alignment between the drug reimbursement lists and the clinical guidelines b) Further develop and update the clinical guidelines based on the international guidelines c) Enforce control over compliance with the prescriptions (e.g. via e-prescription system) and introduce mechanisms to incentivize patient adherence to the prescribed treatment (i.e. reimbursement only in case of regular treatment) d) Ensure personalization of prescribers and regular clinical audit to control compliance with clinical guidelines	MoH Joint Task Force	2014—2020	• Support in development and update of the clinical guidelines based on the international experience
	3.2. Develop the rules for INN / brand name prescription a) Introduce the list of drugs that are to be not considered interchangeable and to be prescribed by brand name including biosimilars and drugs with the narrow therapeutic index	MoH Joint Task Force	2014—2015	• Participation in development of the rules for drug interchangeability and the relevant draft regulations
4. Drug Price Regulation	4.2. Introduce a separate procedure for pricing of original drugs under pilot drug reimbursement projects	MoH Joint Task Force	2014—2015	• Participation in development of the relevant price regulation mechanisms based on international experience • Development of the relevant draft regulations

4. Drug Price Regulation	a) Establish a unit within MoH responsible for price negotiations with original drug manufacturers b) Introduce the pricing of original drugs based on the external price referencing and price negotiations between the MoH and original drug manufacturers c) External price referencing to be based on an average ex-manufacturer drug price in a limited basket of comparable countries with the same currency (e.g. euro) and to be applied at specific time points (e.g. market authorization and loss of exclusivity) d) Introduce a procedure for review of original drug prices based on the negotiations between MoH and drug manufacturers	MoH Joint Task Force	2014–2015	• Participation in development of the relevant price regulation mechanisms based on international experience • Support in development of the guidelines for pharmacoeconomic assessment and pricing of the innovative drugs based on its results • Development of the relevant draft regulations
	4.3. Develop and simplify a procedure for pricing of generic drugs under pilot drug reimbursement projects a) Maximum ex-factory and reference prices of the first generic drug in the market to be defined at a certain level (per cent) below the original drug (e.g. 70% of the price of an original drug) b) Reference prices of follow-on generics in the market to be regulated via internal reference pricing system: reference price of a generic to be defined as a minimum price of a drug with the same INN in Ukraine c) Introduce a procedure for review of generic drugs reference prices based on the actual market prices to ensure commercial sustainability of drug production and cost-efficiency of the drug provision	MoH Joint Task Force	2014–2015	• Participation in development of the relevant price regulation mechanisms based on international experience • Development of the relevant draft regulations
	4.4. Develop a procedure for pricing of biosimilar drugs under the pilot drug reimbursement projects based on the similar principles as for generics	MoH Joint Task Force	2014–2015	• Participation in development of the relevant price regulation mechanisms based on international experience • Development of the relevant draft regulations

5. Financing	5.1. Ensure sufficient financing of the reimbursement programs a) Launch the rolling planning of the drug reimbursement costs and ensure allocation of the target budgets to cover those b) Ensure alignment between the required costs of the drug reimbursement and the available budgets by means of prioritization of programs and introduction of patient co-payment to cover gaps in financing c) Develop mandatory national health insurance system to ensure sufficient financing of the health expenditure including drug reimbursement	MoH Joint Task Force	2014–2020	• Support in planning costs of the drug reimbursement projects
	5.2. Introduce differentiated patient co-payment schemes for drug reimbursement programs a) Introduce differentiated co-payment levels for different population groups to cover gaps in financing between required reimbursement costs and available budgets in order to ensure transparency and controllability of the reimbursement system b) Introduce different levels of co-payment for different types of drugs: • No co-payment for drugs for critical conditions (e.g. HIV, TB, oncology) • Lower co-payment for the drugs for chronicle conditions most critical for Ukraine • Higher co-payment for the rest of drugs in the reimbursement lists c) Define the range of social groups free of co-payment (e.g. infants, pregnant women)	MoH Joint Task Force	2014–2020	• Participation in development of differentiated patient co-payment schemes • Participation in development of the relevant draft regulations
6. Drug Procurement and Dispensing	6.1. Cancel centralized procurement of ambulatory drugs a) For newly introduced drug reimbursement programs avoid centralized procurement using the reimbursement mechanisms instead Exceptions to consider: psychotropic drugs, drugs for HIV and TB	MoH Joint Task Force	2014–2020	• Participation in development of the relevant draft regulations

Category	Element	International Example	CEE Examples		Ukraine
		UK	Estonia	Czech Republic	
1. Population Coverage		• Drug reimbursement is universal for all residents of a country			• De jure, drug reimbursement covers: — Certain benefit-entitled social groups (e.g. war and labour veterans, Chernobyl victims, seniors, children, etc.) — People suffering from certain high-cost nosologies and socially significant diseases (e.g. HIV, cancer, diabetes) — People suffering from hypertension disease (according to the pilot project recently initiated by the government)
		• Certain social groups (e.g. seniors, children) are free of co-payment	• Children younger than three, disabled and patients older than 70 are subject to reduced or no co-payment	• Certain social groups (e.g. neonates, pregnant women) are free of co-payment or subject to the limited co-payment	
2. Drug Coverage	Positive List	• No positive lists • All new prescription drugs are reimbursed unless included in the negative list • The National Health Service (NHS) is obliged to fund reimbursement of all medicines recommended by HTA1) agency	• Unified positive list for both reimbursement and pricing of pharmaceuticals • New drugs are included into the positive drug reimbursement list based on reimbursement applications from drug manufacturers submitted to the health authorities		• Current drug lists include: — Essential Drug List (215 INNs) — used only for price regulation — Drug List used for purchases financed from state or local budgets (784 INNs) — defines the range of drugs that are subject to public procurement and price regulation — Drug List under the Anti-hypertension Pilot Project (10 INNs) — defines the range of drugs that are subject to reimbursement and price regulation under the pilot project • Essential Drug List (EDL) is reviewed upon necessity by a special committee of MoH that includes representatives of MoH, academia, professional medical organizations and physicians • Proposals for inclusion of drugs into the EDL can be presented only by members of the special committee of MoH based on priority diseases
	Negative List	• The negative list includes OTCs and life style drugs as well as drugs which were not recommended for reimbursement by HTA agency	• No negative list		

3. Prescription Policies	Prescription Guidelines	• Clinical guidelines are developed by NICE based on technology appraisals, as well as by specialist medical societies and academia	• Clinical guidelines are developed by specialist medical societies		• Clinical guidelines are under development by MoH in cooperation with medical societies and academia (only 19 guidelines in place)
	Generic/ Biosimilars1) Substitution	• Physicians can prescribe not branded generics as well as brand names • Biosimilars are not interchangeable with their reference products (brand-name prescription)	• Mandatory INN prescription is officially stated, but prescribers still are allowed to prescribe drugs by brand names and prohibit substitution by marking special field for medical reasons • No explicit regulation on the biosimilar prescription	• Physicians can prescribe not branded generics as well as brand names • No explicit regulation on the biosimilar prescription	• INN prescription is mandatory except for biosimilars, reimbursed drugs and drugs provided to a patient free of charge or with a discount, drugs without INN and drugs that are subject to item recording (psychotropic and narcotic drugs)
4. Price Regulation	Prices subject to Control	• Reimbursement prices of reimbursed drugs (i.e. retail selling prices as only fixed co-payment exists)	• Ex-factory prices of reimbursed drugs • Retail and wholesale mark-ups • Reference reimbursement prices (the amount that is reimbursed by the state out of a total drug price)		• Maximum level of wholesale and retail mark-ups of drugs included in the drug lists (please see Mark-ups section) • Under the Anti-hypertension Pilot Project following government regulates: — Maximum level of ex-factory prices — Maximum level of mark-ups — Reference reimbursement prices

4. Price Regulation	Patented Drugs	• Prices for all branded drugs are regulated by The Pharmaceutical Price Regulation Scheme (PPPS) — a voluntary scheme agreed between the Department of Health (DoH) and the Association of the British Pharmaceutical Industry • The PPRS does not regulate prices directly, but limits profits of manufacturers • PPRS is renegotiated every 5 years • Negotiation process is supported by HTA results • For companies which do not participate in the PPRS prices are set based on: — Discounted level of Dec 1st 2008 price — Decision of Secretary of State based on reference prices, costs and other criteria for drugs that were not in circulation as of Dec 1st 2008	• Maximum ex-factory prices of patented drugs are negotiated between the drug manufacturers and MoSA • The recommendations of the PC are used by MoSA in negotiations • External reference pricing is also applied to define the maximum ex-factory prices of patented drugs (please see Reference Pricing section) • No reference reimbursement prices are define for on-patent drugs • Prices of drugs can be reviewed on the initiative of MoSA or a drug manufacturer	• Maximum ex-factory prices of patented drugs are defined by the decision of SUKL based on HTA and external reference pricing • The reference reimbursement prices are defined by SUKL based on the internal reference pricing system and HTA — highly effective drugs can have a premium against the general reference price • The prices of drugs are reviewed twice a year	• No separate procedure for pricing of the patented drugs • As the Anti-hypertension Pilot Project includes only generic drugs, the price regulation of the patented drugs involves only regulation of retail and wholesale mark-ups (please see Mark-ups section)

4. Price Regulation	Generic / Bisosimilar drugs (Let's separate generics and biosimilars	***Note:*** *the following regulation is applied to non-branded prescription generics* • Launch price of a generic must not exceed the original drug price at the moment of the patent expiry • Generic reimbursement prices are reviewed based on either: — Weighted average price of 2 manufacturers and 2 wholesalers before discounts (Scheme A), or — Weighted average price of all manufacturers / wholesalers which submit data about prices, costs and sales to DoH (Schemes M and W) • DoH has a right to intervene into pricing if prices are not reasonable based on information submitted by companies under Schemes M and W	• Maximum ex-factory price and reference reimbursement price of the first generic / biosimilar in the market cannot exceed 70% of the price of the original drug (60% for the second generic / biosimilar; 55% for the 3rd and 4th) • Maximum ex-factory prices of generic / biosimilar drugs are defined based on external reference pricing (please see Reference Pricing section) • Reference reimbursement prices are defined based on the internal reference pricing (please see Reference Pricing section) • Prices of drugs can be reviewed on the initiative of MoSA or a drug manufacturer	• Maximum ex-factory prices of generic / biosimilar drugs are defined based on the external reference pricing system • The reference reimbursement prices of generic / biosimilar drugs are defined based on the internal reference pricing system • The maximum ex-factory price and the reimbursement reference price of a generic / biosimilar drug cannot exceed 68% (generic) or 85% (biosimilar) of the price of the original drug • The prices of drugs are reviewed twice a year	Under the Anti-hypertension Pilot Project • The maximum ex-factory price of a drug is defined as a median between all external reference prices and internal reference prices (please see Reference Pricing section) • The reference reimbursement prices are defined for 3 groups of drugs: — Drug is not reimbursed in case the price of its daily defined dose (DDD) is above the median DDD price calculated based on all external and internal reference prices (first median price level) — The reference reimbursement price of a drug is defined as: Maximum Ex-factory Price × 0.9 × 1.35 in case the price of DDD of a drug is below the first median price level and below the median price level of DDD of all reimbursed drugs (second median price level) — The reference reimbursement prices for the rest of drugs are defined as: Maximum Ex-factory Price × 0.9 × 1.35 × Second Median Price Level / First Median Price Level

4. Price Regulation	Reference Pricing	• No reference pricing used	• External reference pricing — External reference prices can be based on a price of a drug in any EU country, but prices in Lithuania, Hungary and Latvia are usually considered — External reference prices are used to define the maximum ex-factory prices of generic / biosimilar drugs as well as to support the Ministry of Social Affairs in negotiations on the ex-factory prices of patented drugs • Internal reference pricing — Internal reference price is defined as the second lowest price in the price reference group (drugs are grouped at the ATC-5 level (i.e. by the same molecule)) — Internal reference prices define reference reimbursement prices of generic / biosimilar drugs	• External reference pricing — External reference prices are defined as the average between the drug prices in 3 countries with the minimum price level among the EU countries (2 countries in case of highly innovative drugs that are available only in 2 EU countries) — External reference prices are used to define the maximum ex-factory drug prices • Internal reference prices — Internal reference prices are defined as the minimum drug price in the reference group — The reference groups include therapeutically equal drugs (based on ATC-5 level or ATC-4 level in some cases) — Internal reference prices are used to define the reference reimbursement prices of drugs	Under the Anti-hypertension Pilot Project • External reference pricing — External reference prices are defined as the ex-factory drug prices in Bulgaria, Moldova, Poland, Slovakia, Czech Republic, Latvia, Hungary, Serbia (the latter three countries are considered as a back-up in case the drug is not marketed in the first five countries) • Internal reference pricing — Internal reference prices include the registered ex-factory prices, actual ex-factory prices and actual wholesale prices excluding the maximum wholesale mark-up (10%) — Internal reference prices are defined for the groups of drugs with the same INNs — Internal reference pricing is not used to define the reference reimbursement prices in case less than 6 brand names are available for an INN in Ukraine (in practice this condition does not apply to any of the drugs reimbursed under the Anti-hypertension Pilot Project)
	Value Based Pricing	• Value-based pricing system whereby the price of new drugs will be set based on technology appraisal by NICE is currently under consideration • The system is to be implemented by 2014, but delays are expected • Elements of value-based pricing are implemented in price negotiations based on HTA	• Elements of value-based pricing are implemented in pricing decisions based on cost-benefit assessment and price negotiations	• Elements of value-based pricing are implemented in pricing decisions based on cost-benefit assessment and premiums added to the reimbursement levels for drugs with higher effectiveness	• No mechanism of value based pricing in place

4. Price Regulation	Wholesale Mark-ups	• Not regulated directly	• The range of mark-ups is set by the government at the level of 7 — 10%	• The government sets maximum distribution mark-ups — sum of all the mark-ups applied in the distribution chain • The maximum distribution mark-ups vary from 5% to 36% depending on the base price of a drug (regressive mark-up system)	• Maximum mark-ups for drugs included in EDL, purchased by the state or local budgets and for drugs under Anti-hypertension Pilot Project are set at the level of 10%
	Retail Mark-ups	• Government lists retail (reimbursement) prices for reimbursed drugs based on weighted-average manufacturers' and wholesalers' prices • Government pays fees to pharmacies for dispensing services, which are negotiated annually	• The range of mark-ups is set by the government at the level of 21—25%		• Maximum mark-ups for drugs included in EDL vary from 10% to 25% depending on the base price of a drug (regressive mark-up system) • Maximum mark-ups for drugs purchased by the state or local budgets are set at the level of 10% • Maximum mark-ups for drugs under the Anti-hypertension Pilot Project are set at the level of 25%
5. Financing	Sources	• General taxes	• Mandatory health insurance system		• General taxes

5. Financing	Patient Co-payment Schemes	• Fixed prescription fee of GBP 7.40 per prescription in England • No co-payment in Scotland, Wales and Ireland • No co-payment for certain social groups (e.g. seniors, children, etc.)	• Patient pays the difference between the actual drug price and the reference reimbursement price • In addition, the reimbursement list includes four groups of drugs with different co-payment levels depending on a disease severity: — No co-payment — 10% co-payment — 25% co-payment — 50% co-payment • Fixed prescription fee of EEK 20 • Reduced or no co-payment for certain social groups	• Patient pays the difference between the actual drug price and the reference reimbursement price • Fixed prescription fee of CZK 30 (EUR 1.2) per prescription • No or limited co-payment for certain social groups (e.g. neonates, pregnant women)	• 50% co-payment for certain social groups • Co-payment under the Anti-hypertension Pilot Project — patient pays difference between retail and set referent price of a drug
6. Drug Procurement and Dispensing		• No centralized procurement: reimbursable drugs are purchased, distributed and dispensed through commercial supply chain; pharmacies are paid by government for dispensed drugs	• Centralized procurement of drugs for treatment of HIV and TB, opioid-dependence pharmaceuticals and vaccines • No centralized procurement for other drugs	• Centralized procurement of the certain drugs • No centralized procurement for most of the drugs	• Centralized procurement of reimbursable drugs for benefit-entitled social groups and for people suffering from certain socially significant diseases (e.g. HIV, tuberculosis, cancer, etc.) • Under the Anti-hypertension Pilot Project, drugs are purchased, distributed and dispensed through commercial supply chain; pharmacies are paid by the government for dispensed drugs as well as by patients in a form of co-payment

***Source**: BMI; WHO's Health Systems in Transition; WHO Europe; SUKL; Department of Health of UK; Association of British Pharmaceutical Industry; Baker & McKenzie; Orders of the Cabinet of Ministers of Ukraine and the Ministry of Health of Ukraine on the Anti-hypertension Pilot Project; Order of the Cabinet of Ministers of Ukraine as of 17 August 1998 #1303; National Health Programs of Ukraine on specific diseases (HIV/AIDS, Diabetes, Oncology); The Resolution of the Cabinet of Ministers of Ukraine as of 25 March 2009 #333 'On the certain questions of the state regulation of prices of drugs and medicinal products'; PwC analysis*

Lessons learnt from the experience of the CEE and CIS countries that went through the health system transformation

Most of the CEE and CIS countries faced the problem of the discrepancy between the officially stated amounts of the free medical benefits to be provided to citizens and the actual amount of services that could be provided based on the available budgets similar to that of Ukraine. The difficult but inevitable first step in order to ensure proper management of the health system was to reduce the guaranteed set of medical benefits provided to the citizens. Depending on the level of health system under financing the reduction of the amounts of free services involved:

- Reduction of the depth of coverage: introduction of differentiated patient co-payment levels
  - — Such measure was applied by almost all CEE countries, in particular in the reimbursement of the prescription drugs
- Reduction of the scope of coverage: exclusion of the certain services from the guaranteed benefit basket
  - — Almost all the CEE countries excluded certain types of services form the scope of medical benefits (e.g. some dental treatments, spa treatment, etc.); however the countries with the most serious under financing of the system had to reduce the scope of the more demanded services such as limitation of the out-patient drug provision to the certain range of diseases (e.g. in Russia and Ukraine, although both countries demonstrate that the existing ranges are still too broad to cover with available budgets)
- Reduction of the breadth of coverage: exclusion of certain population groups from the coverage
  - — This measure was not used explicitly in any country besides Georgia; Georgia introduced the voluntary health insurance (VHI) system as a primary financing system of the healthcare with only poor population eligible to the free services provision and all the rest required to purchase the VHI in order to have access to health care.

Although politically complicated and challenging, limitation of the medical benefits package is essential for success of the health reforms, as lack of such limitation leads to increase of shadow payments, non-transparency and uncontrollability of the health system, as it can be seen on the example of Hungary

Hungary: Two-step Limitation of the Medical Benefits Package due to Continuing Challenges

Hungary inherited the obligation to cover a virtually comprehensive benefits package. During the first years of health care reforms the government developed a list of covered services that was deep enough to cover nearly all services, with the exception of a moderate negative list. Co-payments for prescribed medicines, medical aids, spa treatments, treatments for aesthetic and recreational purposes were raised significantly.

Despite this, the benefits package was not aligned with available resources, and the tension between increased demand for health care, commitments for free care and the limited available resources required further reform. The imbalances were not addressed explicitly, and instead implicit rationing occurred through queuing, service dilution and informal payments.

Results:

By 1995 the Health Insurance Fund faced a persistent deficit, which eventually became a trigger to decrease the scope and further decrease the depth of the benefits package.

Source: *WHO's Implementing Health Financing Reforms*

While managing the guaranteed benefit package, most of the CEE countries reformed the financing systems to ensure sufficient funding of the health system including drug reimbursement programs. Most of the CEE countries implemented a mandatory health insurance as a principal financing system. Such steps were taken in the first years of the reforms and provided the base for the further health reforms.

Country	Year of the start of the health system reform	Year of the mandatory health insurance introduction
Czech Republic	1991	1992
Lithuania	1991	1997
Poland	1991	1999
Estonia	1990	1992
Slovakia	1993	1994

The further measures to ensure broad drug reimbursement coverage involve the state price regulation which enables budget savings which can be allocated to the expansion of the reimbursement. However, price regulation should be balanced with the general economic environment to avoid the drug shortages, as it can be seen on the example of Poland

Poland: Drug Shortages due to Price Cuts and Parallel Export

Poland's Reimbursement Act, which came into force at the beginning of 2012, was accompanied by challenging price negotiations and the introduction of new regulations which have resulted in major reductions in drug prices.

Since the start of 2012, it has become clear that some medicines are in short supply on the market. The shortage was particularly acute for a certain brand of the insulin — since the drug's price in Poland was among the lowest in Europe, it became clearly a candidate for parallel export. This led to outflow of the most of the insulin to other EU countries leaving the Polish patients without the drug.

Source: *IHS*

Implications for Ukraine

1. Alignment between the drug reimbursement programs implied by the existing regulations and the actual drug provision to patients is the key for transparency and controllability of the reimbursement system. To maintain this several initiatives can be considered:

a) Focus on the reimbursement of the drugs for limited number of the conditions with the gradual expansion

b) Precise rolling planning of the reimbursement costs for existing drug reimbursement programs and prioritization of the different programs (introduction of the patient registers is the critical prerequisite for this initiative)

c) Introduction of the differentiated patient co-payment levels for different population groups to bridge the gap between the costs of the drug reimbursement and the available budgets

d) Cancellation of the centralized procurement of drugs and shift to the reimbursement models to enable higher efficiency of procurement

2. Introduction of the mandatory health insurance is the critical step towards sufficient funding of the reimbursement programs as well as the overall health system. The preparation for introduction of the mandatory health insurance system should be initiated as soon as possible.

3. Although, we see the use of price regulations in some reimbursement systems, and in some projects in Ukraine, it must carefully be balanced with the overall economic environment to avoid drug shortages in the market.

Hospital drug procurement

Why does public procurement system matter?

I. Efficient public procurement system supports innovation, decreases budget costs and ensures high quality of the procured drugs

- Reduction in cost of drug purchasing
  - — Efficient public procurement system reduces cost of drug purchasing due to support of fair competition and volume discounts
- Maintaining quality and supporting innovation
  - — Efficient public procurement system stimulates innovation through creation of demand

for it and ensures high quality through developed purchasing criteria

Key Areas to Address in terms of the Hospital Drug Procurement

Ukrainian hospital drug procurement system has significant gaps in comparison to the best practices analyzed which results in frequent drug shortages in Ukrainian hospitals and thus limited patient access to required treatment. The summary of the key areas to address in the Ukrainian hospital drug procurement system is provided below.

The analysis of the Ukrainian procurement system against the examples of UK, Czech Republic and Estonia is provided in the Best Practice Analysis section.

Key Areas to Address in terms of the Hospital Drug Procurement

Element	Key Success Factors	Key Areas to Address
1. Drug Coverage	1.a) Reimbursable drugs to be listed in the hospital drug formularies developed by hospital pharmaceutical and therapeutic committees independently or on the basis of a regularly updated unified positive list 1.b) Availability of the drugs included into the formularies	• Drug formulary system is underdeveloped • Limited drug provision due to continuous underfinancing of the hospitals and inefficiency and non-transparency of the procurement process
2. Price Regulation	2.a) Same price regulation as in out-patient segment	Please see Ambulatory Drug Reimbursement System
3. Interchangeability	3.a) Full interchangeability of competing products under one tender and no substitution of drugs that are not interchangeable	• No clear rules on forming the state procurement orders for drugs (e.g. by brand name, INN or therapeutic class) • No regulations on interchangeability of drugs

We Propose the Following Roadmap to Address the Key Issues in the Hospital Drug Procurement in Ukraine

Element	Initiative	Initiative owners	Timeline
1. Drug Coverage	Drug Coverage 1.1. Ensure sufficient financing of the hospital drug procurement		
	a) Introduce the healthcare provider contracting system and new payment models in line with the government targets outlined in the Action Plans on the Government Program of Economic Reforms for 2010—2014 to incentivize proper financial management of the hospitals	MoH	2014—2017
	b) Consider introduction of separate target budgets for procurement of the certain high-cost drugs	MoH	2014—2015
	c) Consider introduction of the patient waiting lists for the non-urgent in-patient procedures to reduce the gap between the required costs and available financing in order to increase transparency and controllability of the healthcare system		

1. Drug Coverage	d) Develop the mandatory national health insurance system to ensure sufficient financing of the health expenditure including the hospital drug procurement	MoH	2014—2020
	e) Optimize hospital infrastructure in line with the government targets outlined in the Action Plans on the Government Program of Economic Reforms for 2010—2014 to limit maintenance costs	MoH, Regional Government	2016—2020
	1.2. Ensure control over the drug procurement and transparent administration		
	a) Consider introduction of the obligatory publication of the information on drug availability by hospitals to ensure transparency	MoH	2014—2015
	b) Consider involvement of patient organizations into the control over the drug procurement	MoH, Patient Organizations	
	1.3. Develop the hospital drug formulary system		
	a) Ensure alignment of the hospital drug formularies with National Guidelines and other clinical pathways being developed	MoH, Regional Government	2014—2020
2. Price regulation	Same price regulation as in the out-patient segment (Please see Ambulatory Drug Reimbursement System section)		
3. Drug Interchangeability	4.1. Introduce regulations to ensure full interchangeability of competing products under one tender and no substitution of drugs that are not interchangeable		
	a) Introduce clear rules on forming the state procurement orders for drugs (e.g. by INN)		2014—2015
	b) Introduce the list of drugs that are to be not considered interchangeable and to be prescribed and procured by brand name including biosimilars and drugs with the narrow therapeutic index	MoH	

Best Practice Analysis

Element	International Example	CEE Examples		Ukraine
	UK	Estonia	Czech Republic	
1. Form of Procurement	• Tenders	• Tenders	• Tenders and negotiations	• Tenders
2. Population Coverage	• No national level reimbursement list • Decision on which medicines can be prescribed is made by pharmaceutical and therapeutic committees of hospital trusts based on: — Cost-benefit — Safety — Efficacy — Existing alternatives • Most hospitals have own pharmaceutical formularies, which list reimbursable drugs and are reviewed every 1—2 years	• Separate reimbursement list for hospital pharmaceuticals — In-patient Service List • Most hospitals have own pharmaceutical formularies, which list reimbursable drugs and are reviewed annually • Pharmaceutical formularies are developed by hospital pharmaceutical and therapeutic committees	• Same reimbursement list as in out-patient segment • Most hospitals have own pharmaceutical formularies, which list reimbursable drugs and are reviewed annually • Pharmaceutical formularies are developed by hospital pharmaceutical and therapeutic committees	• Drug list used for purchases financed from state or local budgets defines the range of hospital drugs to be procured • Pharmaceutical formularies are introduced on three levels: state, regional, local • Most hospitals have own pharmaceutical formularies (local), which list drugs that can be prescribed • Local pharmaceutical formularies are developed by the hospital pharmaceutical and therapeutic committees on the basis of the national pharmaceutical register • Despite current legislation that guarantees free of charge inpatient treatment for Ukrainian citizens (including provision of medicines), de facto due to continuous underfinancing hospitals are able to provide free drugs to a limited extend only
3. Price regulation	• Same price regulation as in out-patient sector			

4. Purchaser	• NHS Procurement and Supply Agency (PASA) — most of drugs • Individual hospitals • Hospital purchasing groups	• Individual hospitals — majority of drugs • Ministry of Social Affairs — drugs for TB, HIV/AIDS, opioid-dependence pharmaceuticals, vaccines	• Individual hospitals • In some cases State Institute for Drug Control can conclude the framework agreement with a drug manufacturer that offers the lowest price to supply a drug for a year to all hospitals	• Individual hospitals • Ministry of Healthcare — certain high-cost drugs (e.g. for treatment of TB, HIV/AIDS, oncology and other)
5. Drug Interchangeability	• Biosimilars are not interchangeable with their reference products (brand name admission) • Generics are included into the hospital formularies by INN and are interchangeable	• Mandatory INN prescription is officially stated, but prescribers still are allowed to prescribe drugs by brand names and to prohibit substitution by marking special field for medical reasons • No explicit regulation on the biosimilar prescription	• Physicians prescribe medicines by brand-names in in-patient facilities	• No clear rules on forming the state procurement orders for drugs (e.g. by brand name, INN or therapeutic class) • No regulations on interchangeability of drugs
6. Purchasing Criteria	• Qualification criteria pre-defined in tender documentation • Purchasing criteria include quality, therapeutic benefit and price • Supplier is selected based on the best value-for-money offer	• Supplier is selected based on the best price offer • Qualification criteria can include previous performance in public procurement and financial performance of a supplier		

***Source**: Pharmaceutical Health Information System; WHO; Law on Public Procurement in Ukraine; Order of the MOH of Ukraine from 22.07.2009 № 529; PwC analysis*

Lessons learnt from the experience of the CEE and CIS Countries that went through the health system transformation

As described in the Ambulatory Drug Reimbursement section, most of the CEE and CIS countries faced the problem of discrepancy between the officially stated amounts of the free medical benefits to be provided to citizens and the actual amount of services that could be provided based on the available budgets including provision of pharmaceuticals. However, explicit reduction of the coverage of the free hospital services was generally not applied in any country. The ways to cover the gap between guaranteed benefit package and the available budget include the introduction of patient waiting lists for non-urgent services (e.g. in Moldova) and less frequently introduction of patient fees (e.g. in Latvia).

Similarly to Ukraine most CEE and CIS countries inherited the excessive hospital capacities associated with high maintenance costs. In addition, the main hospital payment mechanism applied in these countries prior to the reforms — allocation of budgets based on hospitals' capacities — did not incentivize efficient use of the financial resources by hospitals' management. Therefore, the important part of the health system transformation agenda was to optimize the hospital capacities and introduce new payment models in order to reduce excessive costs and relocate released financing to other segments including provision of pharmaceuticals.

Country	Number of hospital beds per 1 K population		Implemented hospital payment models
	1990	2010	
Czech Republic	11.3	7.0	DRG, Case-based, Prospective budgets and Individual contracts
Estonia	11.6	5.4	DRG, Per diem and Fee-for-service
Lithuania	12.5	6.8	DRG and Case-based
Latvia	14.1	5.3	Per Diem, Case-based and Fee-for-service

Source: *World Bank; WHO's Health System in Transition series*

Implications for Ukraine

In order to reduce maintenance costs and improve overall financial management of the hospitals and thus increase the available budgets Ukraine should optimize the hospital capacities and introduce new payment mechanisms to incentivize the cost optimization by the hospital management in line with the targets outlined in healthcare programs.

Intellectual property rights

Why intellectual property rights regime is important?

I. Strong intellectual property rights (IP rights) regime increases competitiveness of the pharmaceutical industry through private sector funding, technology development and protection of the local innovation

- Increase in volumes of FDI
  - — The IP rights play a critical role in the ability of the pharmaceutical sector to capitalize on innovation
  - — Robust IP rights protection and enforcement signal reliability and predictability in a market to potential investors, which increases investment attractiveness of a country
  - — While an effective IP rights regime may not be sufficient in-and-of itself to attract pharmaceutical FDI, a weak IP regime can be in some cases a deal-breaker for a technology firm that is looking to invest
- Increase share of technology intensive segments in FDI
  - — Variation in IP rights strength may influence also the nature of the projects financed by the pharmaceutical companies: pharmaceu-

tical companies regard strong IP rights as being more important for decisions concerning transfer of advanced technology than for FDI decisions as a whole

- Support of the local innovative companies
  - — Strong IP rights protection is required to provide incentives for local pharmaceutical companies to invest in R&D and ensure commercial sustainability of the local innovation

II. Strong IP rights regime ensures and accelerates patient access to innovative treatment

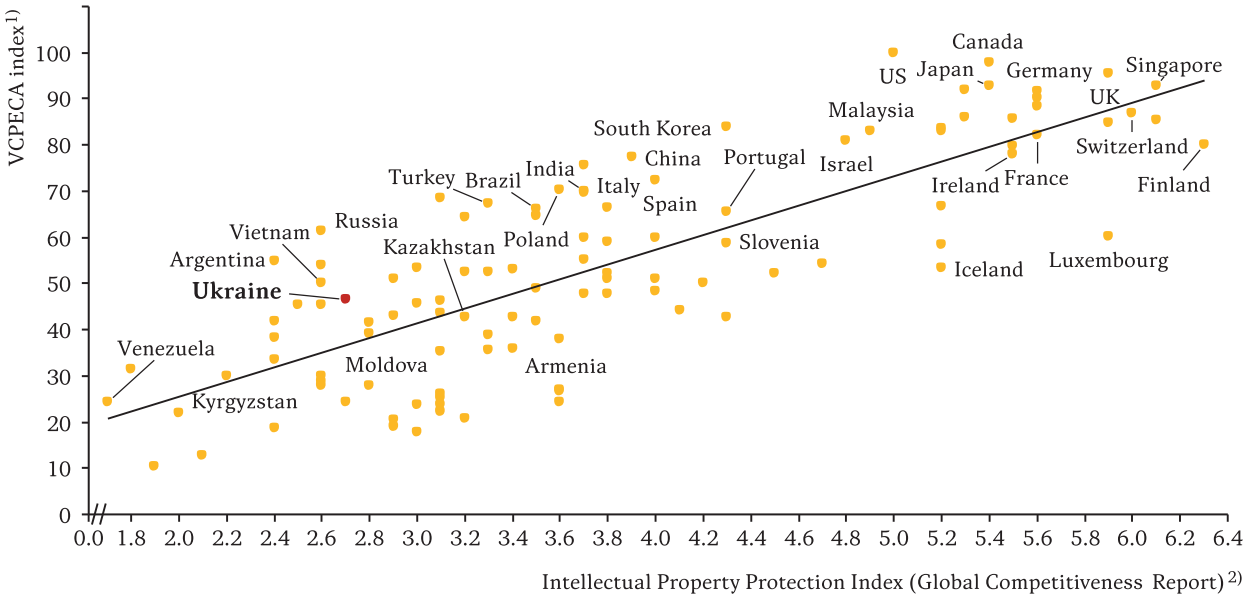
- Fast access to new drugs
  - — Countries with strong IP rights regime are regarded as the first destinations for launch of the new drugs by the innovative pharmaceutical companies and thus patients in such countries receive the accelerated access to innovative treatment

III. Regulatory data protection is one of Ukraine's commitments upon accession to WTO

- Upon accession to WTO, Ukraine is committed to maintain WTO-level of IP rights protection in compliance with TRIPS and TRIPS Plus provisions

Position of Ukraine in terms of IP rights protection

IP Rights Protection Index vs. Venture Capital and Private Equity Country Attractiveness Index



Source: *Global Competitiveness Report 2013; VCPECA Index; PwC analysis*

Note: *1) Venture Capital and Private Equity Country Attractiveness Index: from 0 to 100;*
2) Intellectual Property Protection: 1 = very weak; 7 = very strong

Among other factors IP rights regime plays a critical role in attraction of Private Equity and Venture Capital financing to the country, which in turn drives investment in the pharmaceutical industry. The chart above demonstrates the correlation between the IP rights regime of the different countries and their ability to attract Private Equity and Venture Capital investment. The chart characterizes the IP rights regime and investment attractiveness of the country in general including but not limited to pharmaceutical industry. However, the ability of the country to attract Venture Capital and Private Equity investments is especially important for the pharmaceutical industry especially in terms of R&D.

As can be seen from the chart, Ukraine lags behind other countries, both developed and developing, in terms of IP rights protection, which has a negative impact on the country's investment attractiveness, which is demonstrated by the low Venture Capital and Private Equity Investment Attractiveness Index.

The most robust IP rights regime is provided by the Europeans countries and the US, as well as Singapore and Japan and some other countries. We have compared the IP rights regime in Ukraine with that of the US and the European Union to identify areas for improvement in the existing IP rights regulation and legal practice in pharmaceutical industry in Ukraine.

The comparative analysis of the IP rights regime of Ukraine, EU and US is provided in the Best Practice Analysis section.

The analysis of the key areas to address in the Ukrainian IP rights regime is provided below.

Key Areas to Address in terms of the intellectual property rights

Element	Key Success Factors	Key Areas to Address
1. Regulatory Data Protection	1.1. Sufficient duration of a regulatory data protection period (8+2+1 years in line with EU practice) to compensate the time lost during the drug approval process	• No additional regulatory data protection period for: – Biological drugs – Orphan drugs – New drug formulations – Paediatric indications
	1.2. Clear grounds under which data exclusivity period may be extended	• Lack of clear criteria on new therapeutic indications that should be approved within first 3 years of marketing in order to get permission for data exclusivity extension
	1.3. Effective mechanism to ensure protection against unfair use of an originator's test data	• De facto, regulatory data protection status of an original drug is not checked during registration of a generic since State Expert Committee (SEC) is not responsible for review of such status during review of a drug registration dossier
2. Patent Rights Enforcement	2.1. Effective mechanism to ensure prevention of premature market access of a generic substitute to an original drug, including prohibition of approval of a generic until the patent of an original drug expires	• Lack of possibility for a patent holder to track and prevent patent infringements at an early stage, before market authorization of a generic substitute • De facto, patent status of an original drug is not checked during registration of a generic since SEC is not responsible for review of such status during review of a drug registration dossier • No efficient mechanism of preliminary injunctions to protect patentees against infringements in the current court practice
	2.2. Clear grounds for application of the compulsory licensing mechanism in line with the TRIPS agreement	• Lack of clear grounds under which the government may apply the compulsory licensing mechanism aligned with WTO conditions for issuing the compulsory licensing under the TRIPS agreement
3. Trademark Protection	3.1. Strong protection of trademarks to ensure that patients are not misled by the similar names of different drugs	• Lack of enforcement of the trademark protection — in some cases generic drug manufacturers register the trade names almost the same to those of drugs which are already in the market

We propose the following roadmap to address the identified gaps in intellectual property rights regime in Ukraine

Element	Initiative	Initiative owners	Timeline	Support that can be provided by pharmaceutical companies
1. Regulatory Data Protection	1.1. Review regulatory data protection periods to harmonize those with the EU regulation:			• Development of the relevant draft amendments to the regulation
	a) Introduce a 8+2+1 year regulatory data protection scheme in line with the EU regulation: — 8 years of the data exclusivity period during which the generic drug manufacturers are not allowed to apply for a registration of a drug based on the abridged application — 2 years of the market exclusivity period during which the generic drug manufacturers are allowed to apply for a registration of a drug based on the abridged application, but cannot receive a marketing authorization based on the abridged application — Additional 1 year of market exclusivity for new therapeutic indications	MoH	2016—2017	
	b) Develop and formalize a set of clear criteria on the new therapeutic indications that should be approved in order to get 1 year of additional data exclusivity period	MoH	2014—2015	
	1.2. Enforce the regulatory data protection mechanism a) Make information on the drugs under registration process publicly available to ensure transparency of the regulatory data protection mechanism b) Introduce a responsibility for the State Expert Centre(SEC) to review regulatory data protection status of an originator drug during review of a generic drug registration dossier		2014—2015	
2. Patent Rights Enforcement	2.1. Develop effective mechanism to enforce patent rights protection a) Make information on the drugs under registration process publicly available to allow an innovator to start a patent infringement case before a generic registration b) Develop a procedure for preliminary injunctions against infringements to be applied in the court practice	MoH, State Intellectual Property Service	2014—2015	• Development of the relevant draft amendments to the regulation
	2.3. Specify grounds for compulsory licensing a) Develop a set of clear criteria under which the government may apply the compulsory licensing mechanism in line with WTO conditions for issuing the compulsory licensing under the TRIPS agreement	MoH	2014—2015	• Development of criteria for application of compulsory licensing mechanism by the government
3. Trademark Protection	3.1. Enforce the trademark protection a) Develop a mechanism to prevent illegal use of confusable drug trade names similar to those of original drugs by generic drug companies	State Intellectual Property Service	2014—2015	• Participation in development of the relevant mechanism

Best practice analysis

Category	Element	EU1)	US	Ukraine
1. Regulatory Data Protection	Duration	• 10 years of exclusivity: — 8 years of data exclusivity — 2 years of market exclusivity • Orphan drugs get 10 years of orphan drug exclusivity • Additional exclusivity periods (added to the main exclusivity period): — +1 year of market exclusivity for new therapeutic indications (including paediatric) — +2 years of orphan drug exclusivity for paediatric orphan drugs • No additional exclusivity period for new drug formulations	• 5 years of exclusivity for small molecule drugs: — 4 years of data exclusivity if there is a patent challenge that is then subject to other approval rules • 12 years of exclusivity for biological drugs — 4 years of data exclusivity — 8 years of market exclusivity • Orphan drugs get 7 years of orphan drug exclusivity • 3 years of market exclusivity for new indications (including paediatric) or new drug formulations of small molecule drugs, if new clinical trials (other than bioequivalence) were required for the approval of those • Additional exclusivity periods: — +6 months of market exclusivity for paediatric studies for biological and small molecule drugs — +6 months of orphan drug exclusivity for paediatric studies for orphan drugs	• 5-year of data exclusivity period • Additional exclusivity periods: — +1 year of data exclusivity in case if a new indication that is more advantageous than the original one is approved within the first three years of marketing • Data exclusivity can only be given if the product is registered in Ukraine within two years of the product's initial registration elsewhere
	Implementation Mechanism	• Generic substitutes or biosimilars cannot apply for market authorisation2) based on abridged application3) during data exclusivity period (8 years) • Generic substitutes or biosimilars can apply for market authorization on the basis of the abridged application after data exclusivity period expiry, but cannot get market authorisation during marketing exclusivity period (+2 years)	• Generic substitutes or biosimilars cannot apply for market authorisation based on abridged application during data exclusivity period (5 years for small molecule drug or 4 years if patent challenge; 4 years for biological drugs) • Biosimilars can apply for marketing authorization on the basis of the abridged application after data exclusivity period expiry, but cannot obtain final approval for marketing during marketing exclusivity period based on an abridged application (8 years for biological drugs)	• Generic substitutes or biosimilars cannot apply for market authorisation based on abridged application during data exclusivity period (5 years)

1. Regulatory Data Protection	Implementation Mechanism	• Generic substitutes to orphan drugs cannot apply for market authorisation during the orphan drug exclusivity period (10 years)	• Generic substitutes can apply for marketing authorization on the basis of the abridged application after data exclusivity period expiry (5 years for small molecule drugs/4 years if there is a patent challenge). Generic substitutes that incorporate new indications or new drug formulations covered by a 3 year period of marketing exclusivity (noted above) cannot get regulatory approval to market a product incorporating the new indication or formulation during that period based on an abridged application (3 year period runs from approval of change — new indication or formulation). • Generic substitutes to orphan drugs cannot get market authorisation based on abridged application during the orphan drug exclusivity period (7 years)	
2. Patent Rights Enforcement	Implementation Mechanism	• Producers of generic drugs can apply for and get market authorisation before expiry of a patent of an original drug in case the regulatory data protection period expired (see section 1)	• Market authorization of a generic substitute is not permitted until and unless: — Patent on an original drug is expired, or — Patent issue is resolved by court in favor of a generic, or — 30 months since the start of a proceeding pass	• According to the Law on Medicines for marketing authorization of generic substitutes or biosimilars, applicant should submit: — Certified copy of the patent or license allowing production and sale of original drug — Document confirming the validity of the patent in Ukraine — Letter stating that the rights protected by the patent or transferred under the license are not violated

Note: *1) Data exclusivity regulation refers to drugs authorised after 2005 (EU regulation harmonisation); 2) According to WHO's Manual for Drug Regulatory Authorities, terms "Marketing Authorization" and "Drug Registration" are analogues; 3) Applications with a reference to clinical and pre-clinical data of an original drug instead of own clinical and pre-clinical test data*

Source: *Directive 2001/83/EC; Regulation (EC) 726/2004; Regulation (EC) No 141/2000, The Law of Ukraine as of 28.04.2013 #123/96-vr "On Medicines; PwC analysis*

2. Patent Rights Enforcement	Implementation Mechanism	• Innovators can apply for preliminary injunctions1) against the patent infringements to the national courts of the EU member states before or in parallel with patent infringement litigation • Decision process on preliminary injunctions is intended to be quick and uses a simplified procedure compared to patent infringement litigation • Non-compliance with the preliminary injunctions is a subject to penalty payments and / or seizure or delivery up of the goods suspected of infringing an IP right	• Preliminary injunctions against infringements are also available	• The marketing authorization of generic substitutes or biosimilars can be refused by the regulatory bodies (MoH) if IP rights protected by the patent are violated as a result of such authorization • There is no efficient mechanism of preliminary injunctions to protect patentees against infringements
	Court System	• Germany example: — Federal Patent Court deals with patent validation, while district courts deal with infringements — Separate trials for patent validation and infringement may allow innovators to apply for preliminary injunctions before decision on patent validity • United European Patent Court is agreed to be established	• Specialized court for patent appeals • No formalized court specialization on patent infringement and patent validation cases • Speed of patent litigation in several district courts is higher than in other, thus innovators can take an advantage in courts that proved to be quicker	• Commercial courts deal with patent validation and patent infringement claims • Ukrainian judges are allowed to bring in external experts to get professional opinion on a particular subject (e.g. patent rights) • Based on the data available for 2011 — '131), no issues were identified in terms of patent litigation capabilities of courts in Ukraine: — 6 patent infringement claims were registered; — 16 cases were resolved, all in favor of originator drugs; — Average duration of the legal process was 4—5 months (compared to 18—24 before 2012)

Note: *1) Data exclusivity regulation refers to drugs authorised after 2005 (EU regulation harmonisation); 2) According to WHO's Manual for Drug Regulatory Authorities, terms "Marketing Authorization" and "Drug Registration" are analogues; 3) Applications with a reference to clinical and pre-clinical data of an original drug instead of own clinical and pre-clinical test data*

Source: *Directive 2001/83/EC; Regulation (EC) 726/2004; Regulation (EC) No 141/2000, The Law of Ukraine as of 28.04.2013 #123/96-vr "On Medicines; PwC analysis*

3. Patent Term	Patent Term Extension	• Drug patent term can be extended by a maximum period of 5 years (Supplementary Patent Certificate) • Duration of the patent term extension is calculated as the period between the date of filing the patent application and the date of the first regulatory approval of a drug in a EU Member State, less five years • Total patent term after extension cannot exceed 15 years • Duration of a Supplementary Patent Certificate can be extended by 6 months in case of conduct of paediatric studies of a drug during a patent term extension period	• Drug patent term can be extended by a maximum period of 5 years • Duration of the patent term extension is calculated as the sum of: — Half of the period of clinical trials (the period between the later of (1) the date of application for conduct of a clinical trial, or (2) the date of grant of the patent and the date of filing of an NDA2) — Period of the regulatory review (the period between the date of filing of the NDA and the date of the NDA approval) • Total patent term after extension cannot exceed 14 years following FDA approval • Patent term can also be extended by the time of delays in review of the patent application	• Patent term for a drug can be extended by a maximum period of 5 years • Duration of the patent term extension is calculated as the period between the date of filing of the patent application and the date of the regulatory approval of a drug in Ukraine

Note: *1) According to the data available in the Unified State Register of Court Decisions of Ukraine; 2) NDA — new drug application (application for marketing authorisation of a new drug by FDA)*

Source: *European Patent Convention; Implementing Regulations of the European Patent Convention; European Commission Pharmaceutical Sector Inquiry; Title 35 USC; Intellectual Property Institute of Canada; The Law of Ukraine as of 05.12.2012 #3687-12 "On Protection of Rights to Inventions and Utility Models"; PwC analysis*

Lessons learnt from the experience of the CEE countries

For the majority of the former Soviet Union and former Eastern bloc countries of CEE, IP rights protection is a long-standing problem, due to the previous government's industry policy, which did not recognise patent protection concept.

In order to improve IP rights environment, all CEE countries joining the EU, have aligned domestic legislation according to the EU requirements on patent protection as well as regulatory data protection policies (see section Best Practice Analysis).

Implications for Ukraine

Similar to other CEE countries, Ukraine has taken significant steps toward harmonization of the domestic IP legislation with EU. One of the major recent improvements of the IP regime in Ukraine is introduction of the patent and the regulatory data protection legislation compliant with World Trade Organization's pact on Trade-Related aspects of Intellectual Property Rights (TRIPS). The further step towards the harmonization of the IP rights regulation with the EU practice would be introduction of the 8+2+1 year regulatory data protection period.

The most critical issue for improvement of the IP rights regime in Ukraine is a lack of enforcement of the relevant regulatory data protection and patent legislation, which explains inclusion of Ukraine into the Priority Watch List in the PhRMA's (Pharmaceutical Researchers and Manufacturers of America) submission to the Special 301 Report of the Office of the United States Trade Representative assessing the IP rights regime in the different countries. Therefore, despite significant steps towards harmonization of the IP rights legislation, its enforcement is critical for improvement of the IP rights environment in Ukraine.

Continuing medical education

Why continuing medical education is important?

I. Continuing medical education improves skill level of healthcare professionals, which results in better treatment outcomes, which in turn produces health and economic gains

- Roll-out of new treatment methods
  - — Continuing medical education (CME) allows physicians to keep up with rapid development of treatment methods through constant update of knowledge and practical skills
- Sharing knowledge and experience between healthcare professionals
  - — CME allows healthcare professionals to share knowledge, experience and skills through participation in meetings, discussions and conferences which is essential for improvement of skill level
- Expanding and Deepening Knowledge of Healthcare Professionals
  - — CME allows healthcare professionals to expand their areas of knowledge and skills as well as to continue development in their specific field after graduation

Ukraine position compared to other countries in terms of continuing medical education

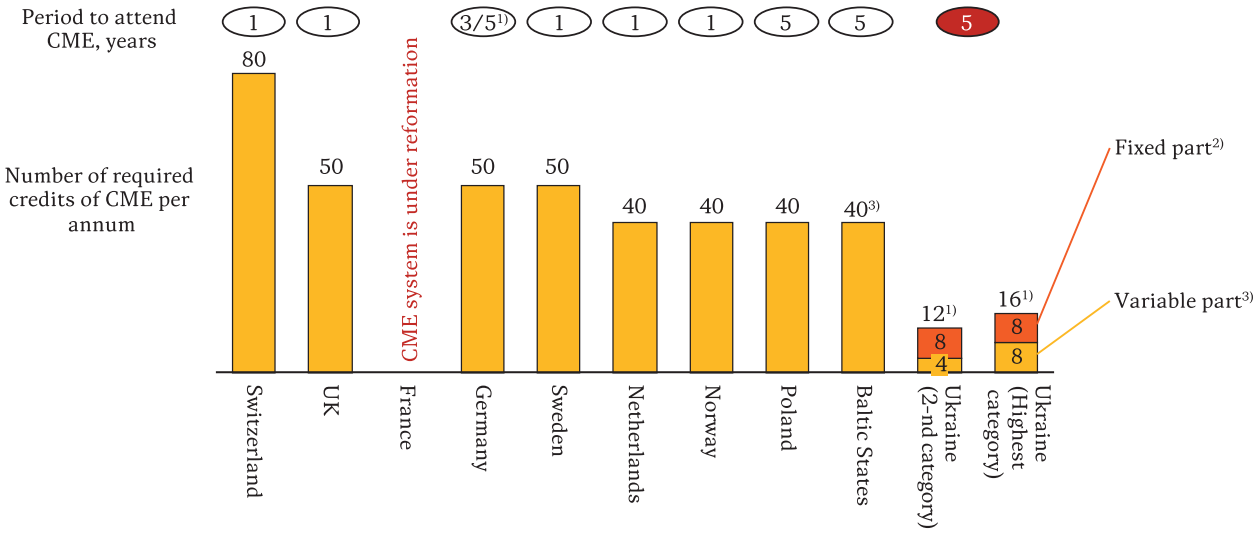
Amount of CME required in Ukraine is less than in other countries and appraisal process required for revalidation is held less often (Ukraine — every 5 years vs. majority of the EU member states — every year), which may negatively affect physicians' professional qualifications as well as overall treatment results.

Despite recent introduction of the CME credit-based system, some critics believe that current attestation process is still more of a formality than a matter of actual performance evaluation as physicians' proficiency "is weighted" based mostly on length of employment, readiness to pass pre-attestation courses, and to submit necessary reports and recommendations.

Key concerns of the academia representatives are focused on the composition of attestation commissions, which often include representatives of administrative officials who are not able to adequately evaluate qualifications and competences of health care practitioners. Also they have been voicing concerns with regards to the lack of clear requirements on accredited CME activities. For example, according to the current CME regulations, credit points may be acquired for publishing medical articles however there is no specific requirement towards the level of a publisher, etc.

Moreover, academia representatives believe that number of the practical based training and workshops should be increased to facilitate knowledge sharing and introduction of the latest industry trends.

Requirements to physicians in terms of CME in selected countries, 2013



Note: *1) From 2014 on the amount of CME credits required for health care practitioners' attestation in Ukraine is 60 credits for the second medical category, 70 for the first and 80 for the supreme; the amount of credits must be collected during 5 years before the next attestation;*

2) Credits for fixed part of CME are granted for completion of mandatory intramural educational courses — this part of CME in Ukraine is not comparable to other European countries in terms of required number of credits;

3) Credits for variable part of CME are granted for participation in training, conferences, meetings, discussions, teaching, authorship and other activities — this part of CME in Ukraine is comparable to other European countries in terms of required number of credits (e.g. up to 8 credits are granted for online courses in Switzerland vs. 10 in Ukraine, up to 8 credits are granted in Switzerland for publications in peer reviewed journals vs. 5–10 in Ukraine)

Source: *Journal of European CME; UK General Medical Council Intelligence Unit; Institute for CME of FMBA; The Resolution of the Cabinet of Ministers of Ukraine as of 19 December 1997 #359 "On Further improvement of healthcare practitioners' attestation"; The resolution of Ministry of Health of Ukraine as of 18 May 1994 #73 "On Approval of the regulations on examinations at the pre-attestation cycles"; PwC analysis*

Key Areas to Address in terms of the continuing medical education

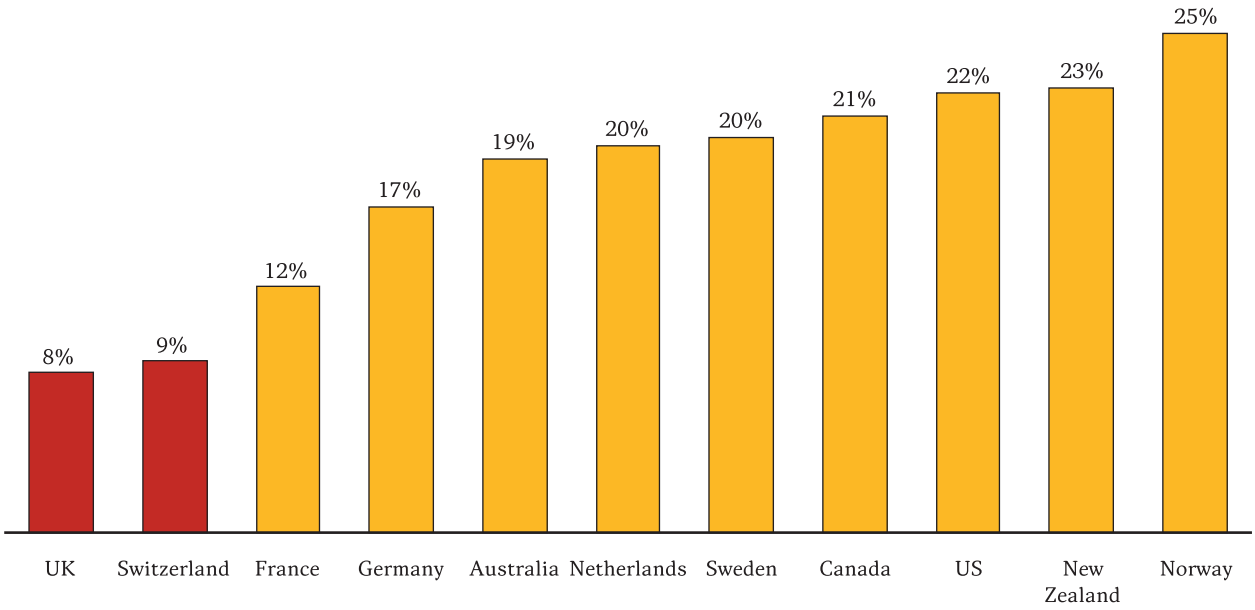
Element	Key Success Factors	Key Areas to Address
1. Amount and Content of Programs	At least 50 credits of CME per annum to ensure continuity of education	• Insufficient amount of CME required • Appraisal process takes place only once in 5 years which means no real continuity exist • Composition of attestation commission — some of the members may not have sufficient level of expertise to evaluate level of qualifications of a healthcare practitioner (e.g. administrative officials)
2. Program Evaluation	Evaluation of CME programs by participants (i.e. Healthcare providers)	• Lack of effective mechanism for feedback collection which would have an impact on educational programs or providers
3. Role of Business	Involvement of pharmaceutical companies in sponsorship of CME events	• No industry-wide code of practice regulating sponsorship of educational events • No clear guidelines on the level of sponsorship fee with regards to the type of educational events
4. e-Courses	Integrated web-based solution for CME	• Lack of online educational programs • Limited internet access of physicians and hospitals • The problem is especially critical for Ukraine because physicians do not always have an opportunity to travel to the places where CME events are held
5. International Integration	Participation of physicians in international CME events	• Lack of mechanism for recognition of participation in international medical events (hosted abroad) as CME • Insufficient knowledge of English by physicians is one of the major obstacle in this direction

We propose the following roadmap to address the identified gaps in the continuing medical education in Ukraine

Element	Initiative	Initiative owners	Timeline	Support that can be provided by pharmaceutical companies
1. Amount and Content of Programs	1.1. Review the amount and frequency of CME required a) Consider increasing the amount of the variable part of CME required b) Review frequency of the health care practitioners appraisal process	MoH	2014—2015	• Advice on the CME system design based on the international experience • Development of the relevant draft amendments to the regulation
	1.2. Optional: transfer the function of HCPs' attestation to medical societies to ensure that attestation commissions are comprised of the medical experts with the relevant and sufficient knowledge to adequately evaluate qualifications and competences	MoH	2016—2017	
2. Program Evaluation	2.3. Ensure constant evaluation of CME programs by participants and incorporation of feedback	MoH, CME providers	2014—2015	• Collection of the feedback on the CME events supported by the pharmaceutical business
3. Role of Business	3.4. Ensure efficient participation of business in the CME process a) Coordinate development and implementation of CME programs with pharmaceutical companies through a relevant joint task force b) Introduce industry-wide code of practice regulating sponsorship of educational events c) Develop and implement guidelines on the level of sponsorship fee depending on the type of educational event	MoH, Industry	2014—2015	• Support of the CME events in the most critical areas based on the dialogue with the government and medical society • Development of the industry-wide code of practice and guidelines on the level of sponsorship fee
4. e-Courses	4.1. Develop online educational Programs a) Improve content of the existing CME web platform through development of online educational programs b) Expand access to the internet in hospitals	MoH, CME providers, Industry	2016—2017	• Participation in development of the online CME Programs

Best practice analysis

Medical, Medication, or Lab Test Errors in 2010–'11[1], %



Source: *The Commonwealth Fund International Health Policy Surveys*

Note: *1) Reported medical mistake, medication error, and/or lab test error or delay*

Unfortunately there is no official statistics on the medical mistakes available for Ukraine.

Based on the available data on the medical mistakes in different countries, we have identified the UK and Switzerland as best practices in terms of continuing medical education. We compared the Ukrainian system of continuing medical education with the systems of these two countries to identify gaps in the Ukrainian practice.

The comparative analysis of the Ukrainian, UK and Swiss system of continuing medical education is provided below.

Best Practice Analysis

Element	Switzerland	UK	Ukraine
1. Performance Evaluation based on CME	• Compulsory — required for membership in medical association, which is critical for practice	• Compulsory — a part of annual appraisals required for revalidation every 5 years	• Compulsory — a part of appraisal process required for revalidation every 5 years
2. Amount and Content of Programs	Amount and Content of Programs • 80 credits per year — 30 credits for self-study — 25 credits for general CME — 25 credits for specialist CME • Credits are granted for participation in courses, meetings, discussions, teaching, authorship, etc.	• 50 credits per year is recommended as a minimum • CME should include external, local and self study activities • Credits are granted for participation in courses, meetings, discussions, teaching, authorship, etc.	• Amount of CME activities to be completed during 5 year revalidation cycle varies depending on the category of the health care practitioner • From 2014 on the following minimum amounts of CME credits are required to be acquired by practitioners during 5-year periods for attestation: — 2nd category — 60 credits (56 in 2013) — 1st category — 70 credits (64 in 2013) — Highest category — 80 credits (72 in 2013) • CME program consists of fixed (40 credits for all categories) and variable parts: — Credits for fixed part of CME are granted for completion of mandatory intramural educational courses introduced by Medical Academy of Postgraduate Education and Postgraduate Faculties of Medical Universities — Credits for variable part of CME are granted for participation in training, conferences, meetings, discussions, teaching, authorship, etc.
3. Providers	• Medical Societies • SIME1) • State Societies	• Royal Medical Colleges and Faculties (e.g. Royal College of Opthalmologists)	• Medical Academy of Postgraduate Education, Postgraduate Faculties of Medical Universities
4. Recognition of Events	• Events are recognized as CME by SIME, Specialist Societies and State Societies	• Events are recognized as CME by Royal Medical Colleges	• Local and international events hosted in Ukraine are recognized as CME by Ukrainian Centre of Scientific Medical Information and Patent Licencing (MOH)

5. Evaluation	• Mandatory program evaluation by the participants		• There is no mechanism for programs evaluations by participates
6. Role of Business	• Events sponsored by business (such as conferences, meetings, etc.) are recognized as CME • Sponsorship of CME events by business is regulated by the industry-wide code of practice including requirements to the content of the events to be fair, objective, balanced, allow expression of diverse theories and recognized opinions and consist of medical or scientific information		• Events sponsored by business are recognized as CME • No industry-wide code of practice regulating sponsorship of educational events
7. Courses	• Unified web-platform for CME	• Project e-Learning for Healthcare	• Despite existence of the unified CME web-platform, there is shortage of the CME e-learning available
8. International Integration	• Participation in European CME events accredited by the European Accreditation Council for Continuing Medical Education is recognized as CME		• Lack of guidelines with regards to European medical events that are recognized as CME events

Note: *1) Swiss Institute of Medical Education*

Source: *Swiss Institute of Medical Education; UK General Medical Council; UK Academy of Medical Royal Colleges; MoH Ukraine; Order of the Ministry of Health of Ukraine № 484 from 07.07.2009; PwC analysis*

Lessons learnt from the experience of other CEE countries

As progress in medicine becomes even faster, there is an increasing emphasis on the importance of continuing medical education as well as continuing professional development throughout the EU region. Therefore majority of the CEE countries (e.g. Poland, Czech Republic, Lithuania) that went through the health care transition, have introduced continuing medical education programs as an obligatory condition of renewal of the licence to practice.

This obligation can be fulfilled through evidence of acquiring a number of credit points for continuing medical educational activities. These are normally awarded on the basis of certified activities, such as attendance at formal education Programs, study visits to institutions, attendance at international conferences, giving "invited" lectures, published medical articles or books etc. Failure to carry out these obligations can lead to sanctions, which may result in modification or suspension of the license, or even its withdrawal.

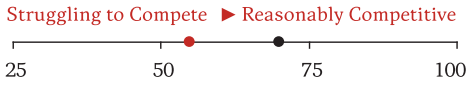
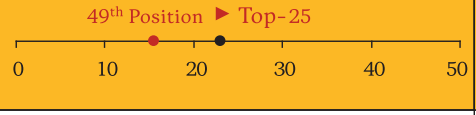
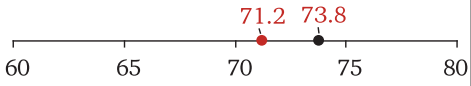
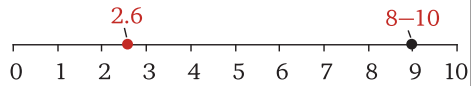
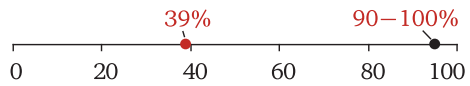
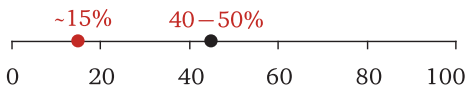
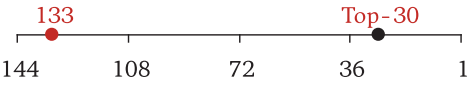
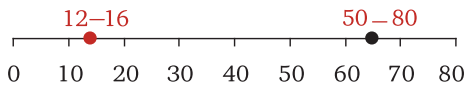
Source: *PwC analysis based on WHO's report "Regulation and licensing of physicians in the EU Region", 2005*

Implications for Ukraine

Ukraine has taken significant steps towards harmonization of the requirements to and guidelines on continuing medical education with EU in line with the experience of other CEE countries. To ensure continuous professional development of the health care practitioners Ukraine needs to make further improvements:

- Increase amount of CME activities as well as frequency of the performance's review to ensure continuity of the professional development
- Ensure constant evaluation of CME programs by participants
- Increase number of online educational programs
- Encourage participation in international CME events

9 BASIC INDICATORS OF SUCCESS OF THE VISION 2020 RECOMMENDATIONS

Key Success Indicators	Vision 2020 vs. Current Status (2012)	Comments
Overall Country Performance		
Country's relative competitiveness according to the BCI Survey		To reach the level of developed
Country's rank in the Scientific American Worldview Scorecard		To reach the level of developed countries
• Life expectancy at birth, years		To reach the level of developed countries
Clinical Trial Environment		
• Number of international interventional clinical trials per million of population initiated per year		To reach the average European countries' level
System to Approve New Drugs		
• Share of the drugs authorized in EU that are registered in Ukraine, % of total number of INNs		To make most of the drugs authorized in EU available to the Ukrainian patients
Public Drug Provision		
• Share of public spending in total drug expenditure, %		To reach the average level of the CEE countries
Intellectual Property Rights		
• Country's position in Intellectual Property Protection Index (Global Competitiveness Report)		To reach the level of best practices
Continuing Medical Education		
• Number of hours of CME required for revalidation of the physicians per year		To reach the level of the best practice EU countries

● — Current Ukraine's position in a metric; ● — Ukraine's position in a metric according to Vision 2020 targets

10 STAKEHOLDERS WHO COMMENTED ON AND CONTRIBUTED TO VISION 2020 REPORT

Government authorities

President's Administration

Verkhovna Rada

Ministry of Health

State Administration of Ukraine on Medicinal Products

State Expert Center

Ministry of Foreign Affairs

Industry

11 APPENDIX

Glossary

BCI	Biopharmaceutical Competitiveness Index
BMI	Business Monitor International
CME	Continuing medical education
CT	Clinical Trial
EC	Ethical Committee
FDI	Foreign Direct Investment
GCP	Good Clinical Practice
GDP	Gross Domestic Product
HTA	Health Technology Assessment
ICH	International Conference on Harmonization of Technical Requirement for Registration of Pharmaceuticals for Human Use
MoF	Ministry of Finance
MoH	Ministry of Health
ppp	Purchasing Power Parity
TRIPS	Trade-Related Aspects of Intellectual Property Rights
WHO	World Health Organization
WTO	World Trade Organization

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- Martijn leads the Strategy and Operations group for Consumer, Pharma and Industrial Products in Russia and has over 16 years of experience in strategy consulting
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