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The Innovation Potential of Bulgaria: Opportunities and Challenges

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This report is published with financial support from the European Commission through its Representation in Bulgaria. The present publication reflects only the views of its authors and the European Commission is not liable for any use that may be made of the information contained therein.

ISSN: 1313-1060

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LIST OF ABBREVIATIONS

AA	– Agricultural Academy
ARC Fund	– Applied Research and Communications Fund
ARPharM	– Association of Research-based Pharmaceutical Manufacturers in Bulgaria
BAS	– Bulgarian Academy of Sciences
BERD	– Business Expenditure on R&D
BGN	– Bulgarian levs
BNB	– Bulgarian National Bank
BPO	– Bulgarian Patent Office
BPM	– Business process management
BRIC	– Brazil, Russia, India and China
BSMEPA	– Bulgarian Small and Medium Enterprises Promotion Agency
CIP	– Competitiveness and Innovation Programme
CIS	– Community Innovation Survey
CMO	– Contract manufacture organisations
COSME	– The Competitiveness of Enterprises and SMEs
COST	– European Cooperation in Science and Technology
CR	– Commercial Registry
CRM	– Customer relationship management
CRO	– Contract research organisations
CSO	– Contract sales organisations
DAE	– Digital Agenda for Europe
EAPVTSC	– Executive Agency for Plant Variety, Testing, Approbation and Seed Control
EB	– Eurobarometer
EBRD	– European Bank for Reconstruction and Development
EC	– European Commission
EEA	– European Economic Area
EFPIA	– European Federation of Pharmaceutical Industries and Associations
EIF	– European Investment Fund
EIS	– European Innovation Scoreboard
EPO	– European Patent Office
ERA	– European Research Area
ERP	– Enterprise Resource Planning
EU	– European Union
FDI	– Foreign direct investment
FIEC	– European Construction Industry Federation
FP	– Framework Programme
GCP	– Good Clinical Practice
GDP	– Gross Domestic Product
GERD	– Gross Expenditure on Research and Development
GVA	– Gross Value Added
ICT	– Information and Communication Technologies
IMI	– Innovative Medicines Initiative
INA	– Survey of Innovation Activity of Bulgarian Business conducted by the Applied Research and Communications Fund
IP	– Intellectual Property
IPC	– International Patent Classification
IT	– Information Technologies
IUS	– Innovation Union Scoreboard
JEREMIE	– Joint European Resources for Micro to Medium Enterprises
JSC	– Joint-Stock Company
LAN	– Local Area Network
LLC	– Limited Liability Company
MEE	– Ministry of Economy and Energy
MES	– Ministry of Education and Science
NACE	– Statistical Classification of Economic Activities in the European Community
NEAA	– National Evaluation and Accreditation Agency
NEC	– National Electricity Company
NGO	– Non-governmental organisation
NIF	– National Innovation Fund
NRA	– National Revenue Agency
NSF	– National Science Fund
NSI	– National Statistical Institute
NSSI	– National Social Security Institute
NUTS	– Nomenclature of Territorial Units for Statistics
OECD	– Organisation for Economic Cooperation and Development
OP	– Operational Programme
PPP	– Public-private partnership
R&D	– Research and development
RES	– Renewable energy sources
SCI	– Science Citation Index
SITC	– Standard International Trade Classification
SMEs	– Small and Medium-Sized Enterprises
SMJSC	– Single Member Joint Stock Company
SMLLC	– Single Member Limited Liability Company
ST	– Sole Trader
SU	– Sofia University
TRIP	– The Agreement on Trade Related Aspects of Intellectual Property Rights
UMIS	– Unified Information System for Management and Monitoring of EU Structural Instruments in Bulgaria
USPTO	– US Patent and Trademark Office
VAT	– Value Added Tax

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EXECUTIVE SUMMARY

National Innovation Policy

The eve of the new 2014 – 2020 programming period in the European Union is rife with promises at a time when assessing the achievement of the objectives of the preceding period are yet to be made. In the last year, the political messages of the three Bulgarian governments in the field of research, technological development and innovations have been distilled in the drafts of the operational programmes Innovation and Competitiveness and Science and Education for Smart Growth, and in the Innovation Strategy for Smart Specialisation, all of which have the ambition to address almost the entire set of financial and non-financial instruments for promoting innovation in the country.

The drafting of these documents has revealed a number of **features of the national policy making** in this field:

- **Contrary to the idea of the European Commission to make regional competitive advantages a priority**, the Innovation Strategy for Smart Specialisation **is drafted at the national level**. It does not allow sufficient identification of the sources of competitive growth unique for the individual regions and local communities in Bulgaria, which would allow the drafting of a specific set of measures for their development.
- The Innovation Strategy for Smart Growth **comes in response to the EC requirements for member countries**, thus **saving the government the effort on updating the existing or preparing an entirely new strategy for innovation growth**.
- The three documents maintain the split in the design and delivery of the policy on the development of science, technology and innovations among various ministries and **build no bridges across these otherwise naturally connected and overlapping fields**.

Piecemeal institutional reforms will not allow the country's innovation system to emerge from its present dire state. Since 2004, the annual *Innovation.bg* report of the Applied Research and Communications Fund (ARC Fund) has provided

an assessment of the innovation potential of the Bulgarian economy using a methodology tailored to the economic realities in the country and the latest international models in the field. The recommendations of *Innovation.bg* for the improvement of the national policy in the field of innovations can be summarised as follows:

- adoption of **an integrated national strategy with a focus on the interaction** among **science, education and innovation** and with a limited number of priorities and focused funding;
- **merging the numerous government units for implementation and funding of R&D and innovations scattered** across the ministries of economy, education and science and the Council of Ministers into a single administrative structure, similar to Innovation Norway;
- providing **prioritised national co-funding for Bulgarian organisations which have succeeded in bringing in funds** for research and innovations **from the European framework programmes**;
- adoption of an **at least three-year horizon for planning national funding for research and innovations**, and linking government funding to clear expectations for results and products. Introduction of **internationally acknowledged rules for annual evaluation of scientific results** of government-funded research organisations;
- prioritised implementation of projects funded under the JEREMIE programme and Techno Park Sofia, and introduction of additional measures for **promoting business innovation in the high-tech sectors**;
- **prioritisation of measures for technological and innovation development in the traditional sectors** such as tourism, textiles, construction and agriculture;
- special focus on measures for **encouraging innovation among low-tech micro and small enterprises** by the introduction of grant schemes providing smaller grants (up to BGN 100,000 and up to BGN 300,000) but covering up to 80 % of costs;
- promotion of measures in **support of a culture of innovation**, such as funding school and student projects (up to BGN 5,000) and of various public events in support of innovations like museums and international forums, among others.

Innovation Potential of the Bulgarian Economy

In recent years, a stable macro-economic environment in Bulgaria has been combined with **very low performance by innovation potential indicators** (quality of research projects, business expenditure for R&D, interaction between universities and business in the field of R&D) which are also the weakest factor contributing to the competitiveness of the Bulgarian economy.

The EU Innovation Union Scoreboard, providing the first official and internationally comparable data about the effect of the crisis on innovations in Europe and the potential of the economies for growth over the next decade, shows that **the most severe decline was registered for Bulgaria which now ranks last in the EU**.

Analysis of the raising and expenditure of funds for science, technological development and innovations in Bulgaria reveals unfavourable trends which are exacerbating despite EU policy and the ambitious objectives set by the Bulgarian government:

- **reduction of public funds for R&D** to some of the lowest levels in the last 20 years;
- **lack of vision and shortened horizon for planning research funding**, accompanied by considerable **fluctuations in the distribution of funds by scientific areas** and scrapping investments in research infrastructure;
- **expenditure for R&D is concentrated in one region of the country**, which exacerbates internal disproportions and limits the opportunities for smart specialisation on a regional and sectoral basis;
- **the innovation policy is guaranteed mostly by external sources of investment in R&D and innovations**, without a clear-cut commitment in the government budget forecast for public support for either direct funding (subsidies, grants) or indirect promotion (tax incentives) of the innovation of business;
- **corruption, lack of transparency, administrative burdening and lack of monitoring and evaluation procedures** of the distribution and expenditure of public funds for science, technological development and innovations – some of the main factors for young researchers moving abroad.

The radical change which the research and innovation community in Bulgaria needs is possible only after a change of the model of governance of these spheres, including through the application of best practices for promoting research and innovation such as: increasing public funding for R&D; coordination among the measures for funding the different stages of the research and innovation process; introduction of an innovation component in public procurement procedures; design and application of pre-commercial public procurement; introduction of clear mechanisms for monitoring and control of the expenditure of public funds.

Innovation Driven Sectoral Competitiveness

The pharmaceutical industry is identified as one of the priority sectors for Bulgaria on whose basis smart specialisation at regional and national level should be developed. The sector is one of the top 5 in the processing industry by many key indicators. However, **the pharmaceutical companies producing in Bulgaria are generic ones and are oriented towards the low price segment, and local industry offers cheap innovations without high-tech specialisation**.

Fundamental research in the pharmaceutical industry is carried out through intensive interaction between science, education and business, which does not exist in Bulgaria. In fact, very few countries in the world manage to achieve an effective interaction in this sphere. In **Bulgaria there is a combination of a limited market with strict regulation and the lowest prices of medicines in the EU. Many regulatory obstacles frequently hinder the country's positioning in pharmaceutical research**. **Clinical trials**, mainly commissioned by companies in the Association of Research-based Pharmaceutical Manufacturers in Bulgaria (ARPharM), **are the most commonly implemented stage of the innovation process in the country**.

Bulgaria faces the same challenges to innovation by pharmaceutical companies as the rest of the EU member-states. The country also strives to achieve **the lowest prices of medicinal products** in the EU. Important factors are **the small market, the relatively high rate of cost-sharing by patients for medicines reimbursed from public health insurance, and the delay in the introduction of innovative therapies caused by a number of organisational and financial reasons**.

Against this background, any action of the public authorities in respect to the pharmaceutical sector should be aimed at creating a competitive environment which would guarantee that the citizens have access to innovative and safe medicines at acceptable prices without unfounded delay. This includes measures for both the enforcement of fair competition rules and regulations aimed at improving the functioning of the market for the benefit of consumers.

INTRODUCTION

EU priorities in the field of research and innovations for the next programming period are clearly defined in a series of strategic documents in the context of the new approaches to the investment of the structural funds through:

- the Horizon 2020 programme;
- other accompanying financial instruments for the development of research infrastructure;
- support for innovative SMEs;
- smart specialisation

by thematic fields:

- pharmaceutics and health care;
- environmental innovations;
- digital growth;
- bio- and nanotechnologies

and **by implementation tools:**

- cooperation channels;
- public-private partnerships;
- public procurement, including pre-commercial.

Although during the first seven years of the full-fledged membership of Bulgaria **EU priorities were almost directly adopted as national priorities** by Bulgarian governments, this did not result in essential positive changes in the understanding of innovations as a critical factor for long-term sustainable economic growth, for applying a well-designed and transparent innovation policy, for the formation of entrepreneurial and innovation culture, and for boosting the innovation potential of the national economy. On the contrary, Bulgaria lagged behind the rest of the member countries (in absolute and comparative terms) and **the national target in the "R&D as per cent of GDP" indicator of 1.5 % by 2020 seems even more inaccessible**.

Against this backdrop, **the Bulgarian government continues to prepare strategic documents only when required by** the EU (Innovation Strategy for Smart Specialisation) and **puts off real reforms of the national innovation system "for better times"**.

The annual ***Innovation.bg*** **report has provided a reliable assessment of the innovation potential of the Bulgarian economy** and the state and development capacity of the Bulgarian innovation system. It has put forward recommendations for improved public policy on innovation in Bulgaria and the EU by drawing on the latest international theoretical and empirical research while taking into account the specific economic, political, cultural, and institutional framework in which the country's innovation system is operating. During the last nine years *Innovation.bg* has made specific recommendations for the improvement of innovation policy and practice which have been supported by business and science. The lack of concrete sustainable actions by Bulgarian governments on the suggestions made, in spite of their involvement in the process at the highest political level, is indicative of a **serious institutional deficiency in the development and application of policies in this field.**

Innvation.bg examines the dynamics in the performance of the national innovation system over the preceding year and the opportunities for its development in the following one on the basis of five groups of indicators:

- gross innovation product;
- entrepreneurship and innovation networks;
- investment in and financing of innovation;
- human capital for innovation;
- information and communication technologies (ICT).

Innovation.bg changes established notions related to the standard system of indicators for measuring innovation. In turn, the shift of focus to sectoral innovation systems and value added chains is closely related to the concept of open innovations. *Innovation.bg 2013* focuses on the analysis of the **innovation potential of the pharmaceutical sector**.

European and Bulgarian Innovation Policy

Priorities of European policy in research and innovation

In the last few years, the EU has been a territory of an integrated strategic approach to promoting innovation and to using the intellectual capital of member countries comprehensively. Europe is striving to overcome the slowdown in the field of research and innovation through a series of measures oriented both towards the use of common procedures for planning and choosing of priorities, and towards the concrete instruments to achieve them. The Europe 2020 strategy and its main initiative Innovation Union are complemented by the strategies for smart specialisation, the integrated and accompanying financial programmes in the framework of Horizon 2020, the initiatives for introducing a single indicator for measuring the results from innovations, the recommendations for the use of public-private partnerships and introducing pre-commercial procurement, among others. The main focal points are:

European higher education in the world

European universities should be globally oriented and able to tackle the challenges on the global labour market. This is the main message of the **European Higher Education in the World**[1] strategy adopted in July 2013, whose objective is to guarantee that **European university students acquire the necessary skills to make careers internationally, while Europe retains its positions as the most attractive destination for students from other parts of the world**. The strategy was developed in the context of the **Higher Education Modernisation Agenda**,[2] which began in 2011 and which aims to improve the quality and practical application of higher education so that young people may acquire the

[1] European Higher Education in the World, COM(2013) 499 final, Brussels, 11.7.2013.

[2] Supporting growth and jobs – an agenda for the modernisation of Europe's higher education systems, COM(2011) 567 final, Brussels, 20.9.2011.

appropriate skills required on the labour market. The main objectives of the Agenda are:

- Enhance the overall quality of European education by facilitating peer learning, cooperation and comparison with other education providers worldwide;
- Boost innovation and job creation in Europe by attracting internationally mobile students and skilled migrants;
- Broaden horizons, increase employability and prepare students to become global citizens, and
- Influence and engage new audiences in a way that advances the EU's position in the world.

Overall, it is expected that the number of students in the world will increase four-fold, from about 100 million in 2000 to 400 million in 2030, with particularly strong growth in Asia and Latin America. The number of students in the EU exceeds 19 million in 4,000 higher education institutions. Only 15 % of them participate in mobility schemes and succeed in acquiring the necessary skills for employment on a global scale. Europe currently attracts about 45 % of all international students.

The main instrument to achieve the objectives of the Agenda is the new **EU programme for education, training, youth and sport Erasmus+** which will be launched in January 2014 and through which over EUR 400 million are earmarked for support of student mobility and closer cooperation between European universities and their partners across the world. For the first time, the programme will include opportunities for students outside Europe to receive part of their education in European universities and vice versa. A total of 135,000 student and staff exchanges between the EU and the rest of the world will be funded, 100,000 more than under the existing Erasmus Mundus programme.

Open market for researchers by facilitating mobility, support of education and career opportunities

Although researcher mobility contributes to high achievements, there are several obstacles on the way to creating an open European labour market in the field of research:

- lack of a **transparent, open and based on quality criteria selection procedure**, which makes a scientific career less attractive and hampers the mobility of researchers, gender equality and research results;
- legal and administrative barriers hampering the access of foreign citizens/non-residents to national subsidies. Initiatives like **Money Follows Researcher** show how these obstacles can be removed and how member countries and research organisations can facilitate access to and transferability of national subsidies without prejudice to national interests;
- gender inequality, social obstacles, unresolved issues in the recognition of academic diplomas.

Some of the EC initiatives aimed to overcome these include: fostering cooperation and coordination within the EURAXESS Researchers in Motion network; establishment of a European mechanism for accreditation of managerial practices for human resources development in R&D; support of a working group to achieve automatic recognition of comparable qualification; establishment of a Pan-European supplementary pension insurance fund for researchers; change in the procedures for acceptance of third-country citizens for the purpose of research, and others.

Access to technologies and transfer of scientific knowledge

In order to increase the economic impact of research it is necessary to promote open innovations through interaction between research, business and education within the so-called "knowledge triangle," and more specifically knowledge transfer between public R&D institutions and the private sector. Since most transfer channels are digital, easy access to online content and digital services is critical to more intensive academic cooperation.

The intentions of the EC in this respect are to ensure open access to scientific publications and projects funded under Horizon 2020; to adopt guidelines to member countries regarding the access to and storage of research information; to draw up a roadmap for digital infrastructure development; to establish a comprehensive policy approach to open innovations and knowledge transfer; to achieve coordination between stakeholders in the process of preparation of sample contracts for consortia in knowledge transfer.

Transnational cooperation in research and innovation

The EU has initiated a number of actions aimed at increasing the scope and impact of the investments made in research and technological development, intended to overcome the challenges of limited public funds. What has been achieved so far is not much because of the differences between national funding rules and project selection processes, as well as the lack of sufficient political will. The following are required to enable all member countries to take advantage of increased transnational cooperation:

- Definition of common priorities, joint planning initiatives and strategic forecast;
- Participation in joint research programmes on the basis of application procedures shared by member countries with a view to promote competition at the European level and identify national strengths as a first step to further specialisation of member countries;
- Promotion of public-private partnerships through increasing compatibility of national funding rules with European standards;
- Removal of legal and other barriers to the compatibility of national tools for funding joint activities, including cooperation with countries outside the EU.

Funding and effective use of R&D infrastructure

Research results depend on a R&D infrastructure of global stature, including such based on ICT. A modern R&D infrastructure attracts talent and promotes innovation and business opportunities. Guaranteeing national commitments of member countries in respect to the implementation of the European Roadmap for Research Infrastructures continues to be a challenge. According to plan, 60 % of research infrastructure sites of pan-European importance identified in the Roadmap are to be developed by 2015. This requires serious investments which should be made at an optimum cost/quality ratio.

Further, national governments should confirm the financial commitments they have undertaken for the development and utilisation of research infrastructure of pan-European interest within national roadmaps and financing under the structural funds. The removal of legal and other barriers to cross-border access to research infrastructure is also important. To this end, the EC seeks to achieve compatibility among national strategies for specialisation, financing under the

structural funds and the opportunities to participate in projects under Horizon 2020. A Charter of Access setting out common standards and harmonised access rules and conditions for the use of research infrastructure is to be developed and adopted.

Support for research and innovation performing SMEs

In a number of strategic documents (Innovation Union, Horizon 2020 and others) the EC underscores the role of SMEs for overcoming the consequences of the crisis, increasing employment and improving the standard of living in Europe. There is a special focus on the programme Eurostars which aims to overcome the existing fragmentation and division of national research and innovation. The programme was established in 2008 with the participation of all EU member countries and six associated countries. Eurostars supports research and innovation performing SMEs by providing funding for transnational innovation projects according to a 'bottom-up' approach, as well as providing legal and organisational framework.

The specific objectives of Eurostars-2 for the next period are:[3]

- to promote market-oriented transnational research activities in any field of research – performing SMEs, especially those without previous experience in transnational research, leading to the placing of new or improved products, processes and services on the market;
- to contribute to the completion of the European Research Area (ERA) and to increase the accessibility, efficiency and efficacy of public funding for research-performing SMEs in Europe by aligning, harmonising and synchronising the national funding mechanisms.

Digital economy

The existence of a strong digital economy is seen as a critical factor for the growth and competitiveness of the European economy. The focus is on several strategic technologies such as big data and cloud computing as factors for raising productivity and the quality of services.

Recommendations aimed at developing and utilising the potential of the digital economy, as well as increasing the productivity of the European economy and creating new economic activities and high-skill jobs on this basis are made in three basic fields:

- Developing an appropriate statutory framework and encouraging new investments in infrastructure and digital technologies while preserving technological neutrality;
- Encouragement of a single digital market oriented on consumers and enterprises to overcome the fragmentation of national markets on the basis of an improved, predictable and stable legal framework in the whole EU;
- Overcoming the disparities between the demand and supply of skills in the field of digital technology and comprehensive use of digital services by end-users and enterprises.

[3] Proposal for a Decision of the European Parliament and of the Council on the participation of the Union in a Research and Development Programme jointly undertaken by several Member States aimed at supporting research performing small and medium-sized enterprises, Brussels, 10.7.2013, SWD(2013) 243 final.

Regional specialisation

The competitiveness of the European economy is based on the diversification of European regions and the differences between them. Europe still fails to utilise to the full its inherent variety. There is a considerable difference between the potential of regions and the results from its utilisation in the form of specialisation, new jobs and growth of regional economies.[4]

To identify regional priorities for growth and concentration of resources in them, the EC launched an initiative for developing regional strategies for smart growth as a necessary condition which would guarantee effective utilisation of structural funding over the next programming period. Smart specialisation needs to exploit regional diversity, stimulate cooperation across national and regional borders and open up new opportunities by avoiding fragmentation and ensuring that knowledge and technology flow more freely across the EU.[5]

The main instruments for implementation of regional smart specialisation strategies include clusters, centres of excellence, and open access research infrastructure, among others. These are the focus of many programmes for funding research and innovation included in or synchronised with Horizon 2020.

The introduction of joint technological initiatives in the pharmaceutical sector, new technologies in energy, aeronautics, bioeconomy and electronics is expected, **with the efforts needed at the national level too**. The planned initiatives should be complemented with **more coordinated utilisation of the appropriate financial instruments and the application of an integrated approach for transition from research to success on the market**.

Challenges to Bulgaria's innovation policy

In order to complete the European Research Area by the end of 2014 **it is necessary to speed up the structural reforms of the national systems** and to strengthen monitoring on the basis of reliable data provided by member countries. This is the general message of the EC to national governments; the message is supported by the fact that member countries which continue to invest in research and innovation fare much better in the present crisis, and thus gives a clear signal about the priorities at the European level and about the requirements to national policies for growth and the approaches to their design and implementation.

Bulgaria's strategy for smart specialisation by 2020

For the 2014 – 2020 period, the European Commission and EU member countries introduced the availability of strategies for smart specialisation in research and innovation as **a mandatory element of the process of preparation of operational programmes to be financed by European funds**. The process of preparing Bulgaria's Innovation Strategy for Smart Specialisation for the period until 2020 began in the autumn of 2012. The World Bank was chosen by the Bulgarian government as the main partner of the then Ministry of Economy, Energy and

[4] Regional Policy contributing to smart growth in Europe 2020, Brussels, 6.10.2010, COM(2010) 553 final.

[5] Region Policy for Smart Growth in Europe 2020, European Commission, Directorate-General for Regional Policy, 2011.

Tourism in drafting it. **The principal focus of these strategies is the selection of a few priority sectors for the local economy**. Bulgaria's draft strategy was presented for the first time in its full version on 28 May 2013.[6] It identifies the following economic sectors as having a potential for growth:

- mechatronics;
- ICT;
- transport and logistics;
- agriculture and food and wine industry;
- health care;
- creative industries;
- motor vehicles and components,

as well as more traditional sectors with a large share in the Bulgarian economy such as:

- tourism;
- furniture production;
- textiles;
- garment industry.

According to the draft Partnership Agreement of the Republic of Bulgaria of 13 August 2013,[7] enterprises from key sectors for the country will be given a priority, but support will not be limited to them. Other sectors will be supported, too, including export-oriented (without exploitation of basic resources), having high added value or the potential for such, having potential for boosting regional and local development, as well as start-up sectors with a high degree of innovativeness and competitiveness.

ICT policy has been recognised as a horizontal-action policy in all social and economic sectors. The Digital Growth chapter in the draft Innovation Strategy provides for the development of a balanced innovative ecosystem by means of ICT and internet. There are plans for the development of techno parks, clusters, centres of excellence, business incubators, e-infrastructure and e-services, among others. The draft Strategy notes that sustainable digital growth can only be achieved through the coordinated efforts of state institutions, representative organisations of business and civil society. The following strategic documents will be used as a basis: National Programme Digital Bulgaria 2015, the National Strategy for Broadband Access Development 2012 – 2015 and the General Strategy for E-government in the Republic of Bulgaria 2011 – 2015. The measures and activities provided under the national ICT policy, however, should be implemented by involving all stakeholders – state institutions, academia, civil society and business in particular. The lack of a sufficient number of consultations with business at the level of individual firms remains the main deficiency of Bulgarian strategic documents. Another important element, for which improvement should be sought, is the funding of the suggested measures: better combination of special-purpose state funding with European and international funding. The Innovation Strategy for Smart Specialisation was drafted without a national document on which to step on. Bulgaria's previous Innovation Strategy dates from 2004.

[6] Draft Innovation Strategy for Smart Specialisation up to 2020 dated 28 May 2013 http://www.mi.government.bg/files/useruploads/files/ris3_28_05_2013.pdf (in Bulgarian) and annexes, http://www.mi.government.bg/files/useruploads/files/innovations/ris3_28_05_2013__pr.pdf

[7] Draft Partnership Agreement of the Republic of Bulgaria outlining the support from European Structural and Investment Funds for 2014 – 2020 (13 August 2013), http://2020.europe.bg/page.php?c=10&d=25

Table 1. STRATEGIC FRAMEWORK OF BULGARIA'S INNOVATION STRATEGY FOR SMART SPECIALISATION UNTIL 2020

Strategic objective	Priorities	Sub-priorities
FIRST STRATEGIC OBJECTIVE: Raising the competitiveness of the economy by building an environment conducive to innovation and research carried out by people with more specialised and better knowledge and through the wide use of ICT.	Effective and coordinated management of the innovation processes.	
	Fostering the innovation system by developing a modern innovation and research infrastructure, promoting human resources according to the needs of science and industry and introducing specific financial instruments for support.	• Promoting business innovation • Promoting research linked to the needs of industry • Development of research infrastructure • Formation of human capital according to the needs of the economy.
	Support of digital growth and e-government.	• Development of a secure internet environment ensuring attractive e-content and services for business, citizens and government, accessible through high-speed and ultra high-speed connections, and the necessary skills, competencies and confidence for their use. • E-government
SECOND STRATEGIC OBJECTIVE: Effective utilisation of resources, given the reduction of CO_2 emissions and prevention of biodiversity loss, for the purpose of providing for the present and future needs of the population.	Introduction of sustainable models of production and consumption taking into consideration the regeneration capacity of ecosystems and not causing degradation of the environment.	
	Introduction of innovative methods and ideas based on renewable, not finite natural resources, so that every region could benefit from its natural capital.	
Objectives in the process of development	Promotion of innovations in aquaculture Fisheries and aquaculture	

Source: Draft Innovation Strategy for Smart Specialisation.

Challenges for Bulgaria's Innovation Strategy for Smart Specialisation 2020

One of the principal challenges in the implementation of Bulgaria's Innovation Strategy for Smart Specialisation will be related to achieving concrete results through the new smart specialisation approach in key sectors of the Bulgarian economy. European funds remain the principal source of funding for Bulgaria's innovation policy, which hampers the **alignment of funding and national objectives and priorities**. Latest NSI data show that national funding for R&D does not correspond entirely to the priority fields indicated in the National Strategy of Scientific Research 2020. In 2012, the largest share of expenditure for R&D went to medical and health sciences (44 %), followed by technical sciences (24 %), natural sciences (19 %), agricultural sciences (7 %), humanities (4 %) and social sciences (3 %). Low funding for R&D in the agricultural sciences is evident, in spite of the fact that biotechnologies and organic foods are a priority in the National Strategy of Scientific Research and will continue to be a priority according to the Innovation Strategy for Smart Specialisation. Support in the field of

engineering and technological sciences also lags behind when compared to the declared priorities.

The number of staff engaged in R&D is an additional challenge, particularly in some of the suggested priority sectors. For example, R&D staff in medical and health sciences amounted to only 10 % of the total in the country in 2012 (NSI, full-time equivalent), in spite of the concentration of funding and the fact that the sector is a national scientific priority. The share of R&D staff in yet another priority field – agricultural sciences – is also insufficient (16 %), a field that is also defined as an economic priority in the draft Innovation Strategy for Smart Specialisation.

The adoption of the Strategy will have to be followed by reconsideration or co-ordination with other strategic documents. What can be recommended in the field of innovation and science is coordination of economic priorities between the Innovation Strategy and the National Strategy of Scientific Research, particularly in respect to the development of mechatronics, engineering sciences, pharmaceutics and creative industries.

The following **main recommendations** could be summarised:

- Although many government bodies forming and implementing the policy in innovation and science have been established (managing authorities, agencies, national contact points, innovation councils), one of the greatest challenges for Bulgaria remains the **depleted human research capacity** which cannot be restored unless a scientific career is made attractive.
- The existing strategies and financial plans should provide an **alignment between economic and research priorities** and their financing with both European and national funds. Funding under the Cohesion Funds, Horizon 2020 and other European and international initiatives is recommended to focus on the development of research infrastructure. This can be achieved by combining funding from different sources.
- The methods for achieving **synergy between cohesion funding and Horizon 2020** need to be spelled out in more detail in the Innovation Strategy for Smart Specialisation. It is also particularly important to have more intensive cooperation between the government authorities responsible for the implementation of the Strategy and those which are responsible for the development of the European Economic Area (EEA) and the management of initiatives within Horizon 2020.
- Efforts should be stepped up for increasing R&D funding from both the government and business, so as to get closer to the ambitious national objective of 1.5 % of GDP by 2020. Financial support for R&D should focus on sectors with high potential and added value, which have been defined as both economic and research priorities (including the agricultural and bio sectors, for example).
- Support will be needed in the next 4 – 5 years to inaugurate and establish more and effective **technology transfer centres and other intermediary units** which provide the contact between science and business. Technology transfer centres are currently few because their initial funding was suspended and because of a number of difficulties related to finding new financial support. In most cases the centres that are operating rely on their host institutions (universities or other academic bodies) to carry out their activity.

Draft Partnership Agreement of the Republic of Bulgaria outlining the support from European Structural and Investment Funds for 2014 – 2020.

Bulgaria's draft Partnership Agreement formulates four strategic priorities in respect to financial support from all five European funds (ERDF, ESF, the Cohesion Fund, EAFRD and EMFF). Their objective is to achieve the common European goals in Europe 2020 and the EU Danube Region Strategy. The same priorities are also set down in the draft Operational Programme Innovation and Competitiveness 2014 – 2020.

- Strategic Priority 1: Education, qualification and employment for inclusive growth;
- Strategic Priority 2: Research, innovation and investments for smart growth;
- Strategic Priority 3: Cohesion and green economy for sustainable growth;
- Strategic Priority 4 (horizontal): Good governance and access to quality public services.

Table 2. NATIONAL OBJECTIVES IN IMPLEMENTATION OF STRATEGIC PRIORITY 2 OF THE NATIONAL DEVELOPMENT PROGRAMME

		Indicator	Target
Support for innovation and investment to promote the competitiveness of the economy	**Strategic Priority 2: Research, innovation and investments for smart growth**	Share of early school leavers	11 %
		Share of 30-40 year-olds, higher education or equivalent graduates	36 %
		Employment among population aged 20-64	76 %
		Reduction of the number of people living in poverty	260,000
		Expenditure for R&D as % of GDP	1.5 %

Source: Draft Partnership Agreement as of 13.08.2013; National Reform Programme; National Development Programme: Bulgaria 2020.

According to Strategic Priority 2, **support from the European Structural and Investment Funds will focus on achieving smart growth by increasing SME competitiveness and productivity in sectors with high added value and export potential**, development of R&D and innovation, market-oriented activities, effective educational and scientific environment which interacts with business. This aims to develop an **environment allowing quality research, access to and utilisation of ICT**.

Strategic priority 2 includes **three sub-priorities**:

- Increasing SME competitiveness and resource efficiency;
- R&D and innovation;
- Access to and use of ICT.

It should be noted that Bulgaria is still only a "consumer" of the priorities and policies defined by Brussels and their association with the funding received. The country needs to develop **a national position on the main strategic documents related to the funding of science and innovation in the EU**, not only at national but also at European level. For example, it is generally agreed that while European structural funds support cohesion in the EU, some other policies of Brussels are headed in precisely the opposite direction. The framework programmes for research create numerous opportunities for successful relations between scientists in Europe but they are also practically **a one-way ticket for emigration of highly qualified staff from the new member countries to the old ones**.

Box 1. A NEW EU RESEARCH AND INNOVATION POLICY FOR 2014 – 2020

Project funding practice in the EU shows that restrictions are applied to the payment of scientists and experts on national and geographic grounds for projects which generate "European added value" (Lifelong Learning Programme, FP7, Competitiveness and Innovation Programme).[8] This disparity is particularly noticeable in respect to the new member countries (sometimes reaching 10 to 14- fold differences in remuneration) and serves as a catalyst to a process of emigration from these countries. According to the draft Innovation Strategy for Smart Specialisation, version dated 3.09.2013, 80 % of the Bulgarians with doctoral degrees have left the country. In addition, a World Bank report found that by 2050 Bulgaria's working age population will have shrank faster than anywhere else in the world. The decline will be about 45 %, while in "old" Europe it is expected to be about 10 %. With the introduction of differentiation of the payment for researchers and the rest of the participants in the European programmes the **EC places the participants from the new member countries at an extreme disadvantage** and effectively increases brain drain. Thus, new member countries are drained and additionally lose potential for development precisely in the fields of research and innovations which are expected to be a priority in the new programme period 2014 – 2020.

Data about the FP7 budget indicate that **the new member countries are net contributors** under part of the programmes. Publication of official data about the contribution of member countries would throw light on the problem and would be helpful in the search for solutions and coalitions with the rest of the CEE countries.

Along with this, Bulgaria neither has sufficient, nor is developing new project capacity for participation in programmes like Horizon 2020, COSME, Erasmus+ and others at the European level. One of the reasons for this is the low staff cost rate. Some steps for changing the existing discrimination practices could include:

- Put forward a proposal for the application of **a single payment scheme, regardless of nationality, for projects which generate European added value**;
- Establish **an informal project and administrative liaison office in Brussels**, as is the practice of nearly all countries, as well as of a number of municipalities, associations and companies.[9]
- Develop at national and European level a **virtual mobility model** which would become the principal instrument at the forthcoming calls, for example: ERA Chairs/Teaming and Twinning for Excellence;
- Participation of more experts, representatives of new member countries in the preparation of the Financial Guide for Horizon2020 and Erasmus +.
- Actively participate in the drafting of European policies and strategies, and clear definition of the national position and priorities.

Source: ARC Fund, 2013.

[8] http://www.scilogs.com/balkan_science_beat/eus-horizon-2020-should-pay-researchers-in-eastern-europe-the-same-salaries-as-in-western-europe/; http://ec.europa.eu/education/calls/s0112/lump_en.pdf; http://ec.europa.eu/education/llp/doc/call13/part1_en.pdf

[9] http://www.iglortd.org

Draft Operational Programme Innovation and Competitiveness 2014 – 2020

According to preliminary MEE data, the new Operational Programme Innovation and Competitiveness 2014 – 2020 will provide about EUR 2.22 billion for innovation, energy efficiency and support of the competitiveness of enterprises. This is about twice as much as the current OP Competitiveness and amounts to about half of the financial resource of the European Regional Development Fund for Bulgaria in the coming period.

According to the draft Operational Programme Innovation and Competitiveness,[10] support will be focused on four priority axes:

- **PA 1: Entrepreneurship and business development**: Establishment and development of enterprises in Bulgaria through support for technology improvement, increasing competitiveness and raising productivity.
- **PA 2: Innovations**: Promotion of innovation capacity at enterprises, development of innovation infrastructure through support of existing and effective structures, development of cooperation between business and scientific circles.
- **PA 3: Green and energy-efficient economy**: Promotion of energy and resource efficiency of enterprises by introduction of low-carbon technologies, eco-innovations and measures in support of promoting energy efficiency, efficiency in power generation and transmission.
- **PA 4: Internationalisation and services for business**: Establishment and development of effective systems for support and expert assessment at new and/or existing agencies, organisations and authorities though the development of modern and innovative services which will contribute to the competitiveness of enterprises. The priority axis will also support the creation of a favourable innovation and investment business environment, internationalization of the innovation process, internationalisation mainly of SMEs, improving the quality of tourist services and tourist marketing.

The four axes of the programme have been drafted in a way so that each priority axis may correspond to one thematic objective from the general strategic framework of the European Structural and Investment Funds for 2014 – 2020.
The approach of the Operational Programme is based on three principal points:

- **Focus on seven priority sectors** according to the Strategy for Smart Specialisation, particularly in respect to entrepreneurship, although support would not be limited to them;
- **Development of business infrastructure** (techno-parks, laboratories, etc.);
- **Establishment of organisation for cluster coordination**.

Draft Operational Programme Science and Education for Smart Growth 2014 – 2020

This is an additional operational programme proposed for this period which, if adopted and approved, would have to build on the Innovation Strategy for Smart Specialisation and to lend more "muscle" to OP Competitiveness and Innovation. According to its draft version[11] financial support will be focused on

[10] Draft version of Operational Programme Innovations and Entrepreneurship 2014 – 2020 (at July 11, 2013), http://www.opcompetitiveness.bg/module3.php?menu_id=276

[11] Draft Operational Programme Science and Education for Smart Growth 2014 – 2020, http://www.eufunds.bg/bg/page/962

six priority axes, some of which overlap with those of OP Competitiveness and Innovations:

PA 1: Research and technological development: Promotion of research, technological development and innovations.

PA 2: Education for real employment, mobility and entrepreneurship: Promotion of employment and support for workforce mobility.

PA 3: Education, skills and lifelong learning: Investments in education, skills and lifelong learning.

PA 4: Educational environment for active social inclusion: Promotion of social inclusion and fighting poverty.

PA 5: Educational and ICT infrastructure: Improving access to ICT and their utilisation and quality; investments in education, skills and lifelong learning.

PA 6: Transnational cooperation

PA 7: Technical assistance

The suggested operational programme will have to detail very well its concrete measures to distinguish clearly the impact areas in comparison with the other two programmes – Competitiveness and Innovation and Human Resources Development. Without a good synchronization with the other operational programmes **there is a serious risk that this one would increase the rift between innovation and science**.

Challenges and recommendations

Policy recommendations

- The effective utilisation of European funds, including the complementarity of cohesion and Horizon 2020 funding, will require good coordination between the government ministries, which is still lacking. As noted in the draft Strategy for Smart Specialisation, **the fragmented state of the national innovation system is a challenge**. The improvement, therefore, of cooperation between government bodies should be made a priority. The National Innovation Board, suggested by the Strategy is a good opportunity to deal with this problem, although it should not remain simply a consultative body but have the authority to make concrete decisions.
- It is very important to concentrate efforts and resources on the development of **modern research centres** in priority fields for Bulgaria. Through OP Science and Education for Smart Growth efforts will be aimed at the development of a new type of research and technology centres precisely in fields with the potential, experience and capacity for integrating various academic groups. These **Centres of Excellence and Research Competence** would consolidate and expand cooperation between the best scientists, research groups and institutions within a given priority research field; they would generate added value for the development of already established scientific areas and subjects; the results achieved would be

established and an environment for joining resources in the search for a more tangible effect from the research would be created.

- It is necessary to support and encourage the participation of Bulgarian research teams in all European and international research programmes (including Horizon 2020). It is important for Bulgaria to avail itself of the opportunities for European funding of **research infrastructure**. The development of infrastructure would help stop the trend of migration of scientists abroad. In connection to this, **human resources** should be made a priority for the policies for research infrastructure development. It is important to ensure long-term participation in the European Strategy Forum on Research Infrastructures (ESFRI).
- **Technology transfer centres, clusters and business angels** should also receive adequate support and should be developed, as now they still have considerable difficulties in becoming sustainable, particularly that their for-profit operations are limited. The development of a capacity – currently totally lacking – to formulate innovation policy at regional level, incorporating initiatives of municipal and district administrations, is also needed. It could be done by creating an opportunity for growth of regional intermediate bodies under the various operational programmes.
- The approach of smart specialisation which will be applied over the next programme period provides numerous opportunities for **transborder cooperation** with other member countries with which Bulgaria shares specialisation fields and research and economic priorities. Accelerated introduction of innovations through international cooperation can also be achieved through the European Innovation Partnerships initiative put forward by the European Commission, part of Innovation Union's objectives.
- The revisions to the **Investments Promotion Act** are a step in the right direction. Nevertheless, a complete integration of national and external funding, including foreign investments, in the priority fields of the innovation policy is yet to be achieved. It is recommended to specify the role of all programmes, including Horizon 2020 in achieving the objectives of smart specialisation. It is high time to harmonise the various laws dealing with a sustainable innovation environment – for investments, SMEs, research, tax, social insurance and so on, including the adoption of an Innovations Act.
- It is necessary to reconsider the **horizontal policies** and to synchronise policies in respect to education, competitiveness, public procurement, etc.

Recommendations for the approach to the drafting and implementation of the Innovation Strategy for Smart Specialisation:

- The Innovation Strategy for Smart Specialisation should include not only a description of the objectives, but also an **Action Plan** with concrete measures, sources of funding and responsible authorities, deadlines and measurable objectives by which progress on the implementation of the Strategy would be judged.
- **Balance should be sought between the contributions of the government and business** to achieve the objectives of the Strategy successfully.
- The EU cohesion policy for 2014 – 2020 focuses on the planned interventions, determined by **SMART-indicators and with clear targets** through the Common European Framework of Reference. It is necessary to review carefully and to specify the indicators put forward in the draft Innovation Strategy for Smart Specialisation. **A methodology of assessment** needs to be developed for all stages of the Strategy's progress, which should

include both information about the invested funds and **impact indicators**. Impact indicators should include both economic and R&D indicators followed by national and international statistics (NSI, Eurostat), as well as by **social indicators**: living standard, per capita GDP, income levels, purchasing capacity, job opportunities, reduction of regional differences, among others. It is also necessary to specify the **regional aspects** of the Strategy.

Recommendations concerning the approach to preparing and implementing the operational programmes for 2014 – 2020:

- Both the increased budget for innovations, energy efficiency and support of competitiveness, requiring **additional administrative resources**, and the adaptation of the new **principles of smart specialisation** in formulating the procedures under the operational programmes will be an additional challenge in the 2014 – 2020 period.
- It is particularly important to apply the experience accumulated in the implementation of the operational programmes in 2007 – 2013, particularly in respect to **reducing the administrative burden**, for a quick start of the new programmes equipped with the necessary documentation and established procedures for application, reporting and quality control.
- The **electronic submission and reporting of projects** under the operational programmes need to become fully operational.
- Bulgaria's draft (August 2013) Partnership Agreement takes into account the importance of the EU Danube Region Strategy for the **policy of cohesion and the importance of cooperation** at macro-regional level. Bulgaria should seek its role in the new instrument actively with the aim of attracting larger and more effective resources in support of regional development in the country's northern regions.
- The future procedures and projects related to transborder cooperation under the operational programmes should include not only exchange of information and staff **but also joint development and introduction of innovations, development of scientific and research infrastructure**, as well as other forms of cooperation leading to the generation of new research projects or market-ready products.
- The operational programmes should provide a balance between focusing support on a limited number of key projects in the priority fields and funding for a wider range of SMEs, particularly those with less than 15 employees, which so far have not had the administrative opportunity to avail themselves of the cohesion funds.

Recommendations concerning the priorities and thematic focus of funding:

- Besides standard indicators such as export and employment by sectors, priority sectors should also be chosen on the basis of **present and future contracts with major international companies, the existing niches and the opportunities for synergy between sectors**. As a whole, Bulgaria still does not have many large companies which could be regional leaders.
- The choice of priority sectors should be consulted with the business sector which can provide more up-to-date information than national statistics. Currently, several main sectors are usually cited as research priorities, while others are economic priorities in the various national strategic documents, national statistics and economic analyses.
- A balance needs to be struck between **low-tech (or traditional) and high-tech priority sectors** because in most cases low-tech sectors generate more employment and are important for the present stage of development of the Bulgarian economy.

- In addition, demand for some low-tech products (eco-tourism, organic products) could possibly increase in the future. There is also potential to develop **new niche priorities**, with attention focused on:
  - **Organic products**. Bulgaria has unused arable land which provides large opportunities for the development of organic farming.
  - **Health tourism** is a new sector which until recently was not discussed in relation to innovation or economic policy. This is a new, promising sector, which aims to use the demand for cheaper dental and health services in Bulgaria, thereby attracting tourists and developing health-care-related infrastructure.

Table 3. RESEARCH AND ECONOMIC PRIORITIES OR FIELDS WITH COMPETITIVE ADVANTAGES AND POTENTIAL

Research priorities (fields with advantages for development of science and technology)	Economic priorities (with good economic indicators)
• Biotechnologies and organic foods, food industry and agriculture; • Transport and logistics; transport equipment; energy and energy efficiency, green and environment-friendly technologies; natural sciences; • ICT; IT and outsourcing; communications and navigation technologies; computers; software and memory; • New materials and technologies; • Eco-innovations, environment, climate change; • Physics and astronomy.	• Machine-building; • Health care and pharmaceutics; • Chemical industry, biochemistry, rubber and plastic products; • Electric industry and electronics, electric equipment; • Manufacture of metal products (excl. machines and equipment); • Garment industry; • Construction of buildings and specialised construction works; • Other.

Source: MEE, MES, NSI, USPTO, SCOPUS, 2013.

Innovation Potential of the Bulgarian Economy

Gross Innovation Product

The Gross Innovation Product of an economy – its innovativeness – is assessed by the new products and services introduced, the new technologies created and the scientific outputs. It results from the interaction of the innovation, technological and scientific products of a country. It is a major benchmark for innovation policy because it allows decision-makers to compare the outcome of the innovation system in temporal and geographical terms, as well as to estimate the need for changes in the organisation and resources of the innovation process.

Innovation Product

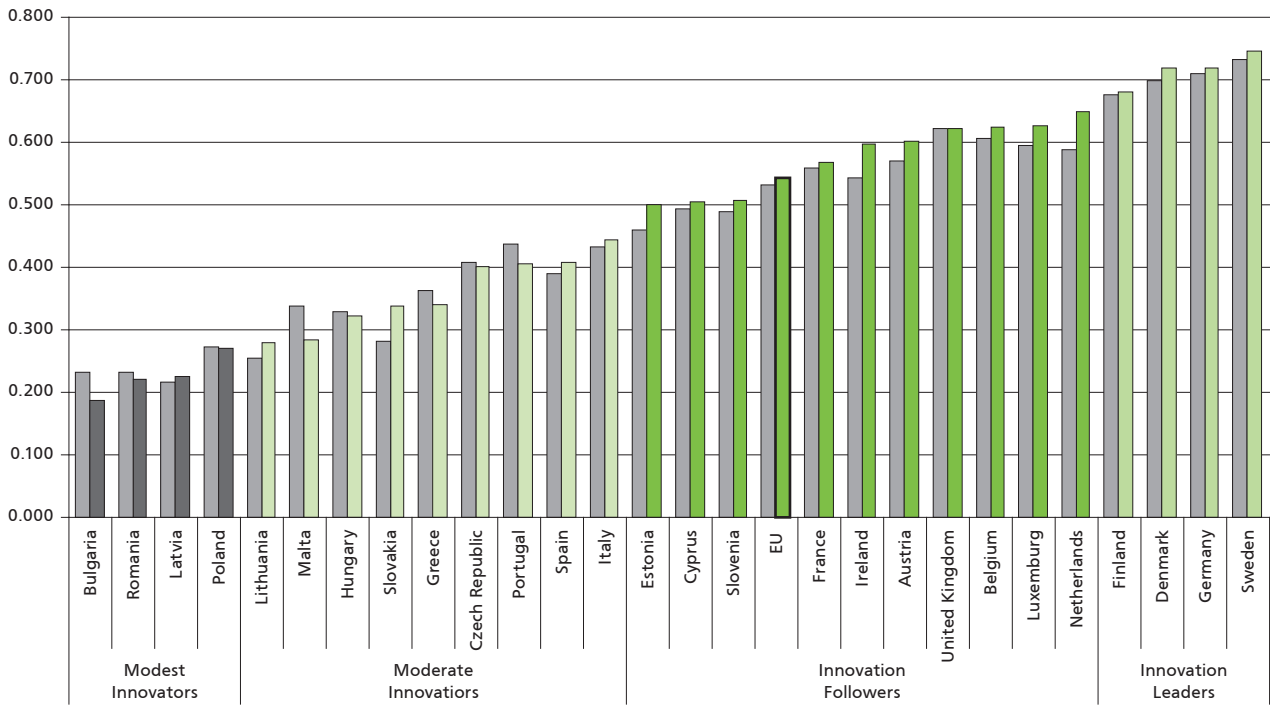
The innovation product results from new and significantly improved processes, products and services based on new and/or adapted knowledge and know-how. It is determined by the innovation activity of enterprises in the country and is the most important indicator for assessing the national innovation system. Innovation activity in business and innovation demand by the people, along with the factors which determine these, comprise the innovation potential of an economy – its capacity to develop on the basis of new knowledge.

Last in innovation in Europe

In the beginning of 2013, the European Commission published the results of the Innovation Union Scoreboard (IUS), a leading initiative of the Europe 2020 Strategy. They reveal that the fast rate of catching up registered by Bulgaria in 2006 – 2010 is over and the country has plummeted in the ranking, trailing the rest of the EU. The index, which measures the condition and quality of research and innovation infrastructure, innovation activity at enterprise level and the economic effect achieved, indicates that Bulgaria's performance has dropped by a staggering 18.7 % in comparison to 2010.

The data, albeit covering a period of two years, are the first official and internationally comparable results about the effect of the crisis on innovation in Europe and the potential for growth of the economies in the next decade. They are a clear sign that, in spite of fiscal stability, the policies of the Bulgarian government have not resolved the long-term problems in the economy. Should this not change, Bulgaria is destined to remain anchored at the bottom in Europe with respect to income. New,

Figure 1. IUS RANKING AND CHANGE OF THE INDEX VALUE COMPARED TO 2010



Source: Innovation Union Scoreboard 2013.

bold and fast decisions are necessary to help the country escape the trap of low competitiveness, poverty and rising social tension.

Key Messages

Although most of the EU27 countries have preserved their positions, an increasing difference between innovation leaders and the other groups has been registered for the first time. Since the launch of the Europe 2020 Innovation Union flagship initiative in 2010, the value of the innovation index has deteriorated in nine countries, most dramatically in Bulgaria. The main reasons for this are the drastic cuts of public funding for science and technological development. In Bulgaria, these were particularly severe in 2010 but the trend also continued in 2011 and 2012. Such actions are in stark contrast with the target officially announced in the National Reform Programme to achieve a level of investments in R&D of 1.5 % of GDP in 2020.

At the European level, the largest annual decline was registered in investment in new machines, equipment, patents and licences by the business sector (5.2 %) and venture capital investments (3.1 %). In most countries, this decline in private investment is largely cushioned by R&D expenditures in the public sector. In view of the continuing crisis in the Eurozone, there will probably be a continuing lagging of Europe behind the USA and a faster catching up by China. In this respect, Bulgaria's closer association with the German-Scandinavian innovation space is a mandatory condition for future growth. The technological investments of Chinese companies in this country should also be considered a positive trend mostly as capital for technological development.

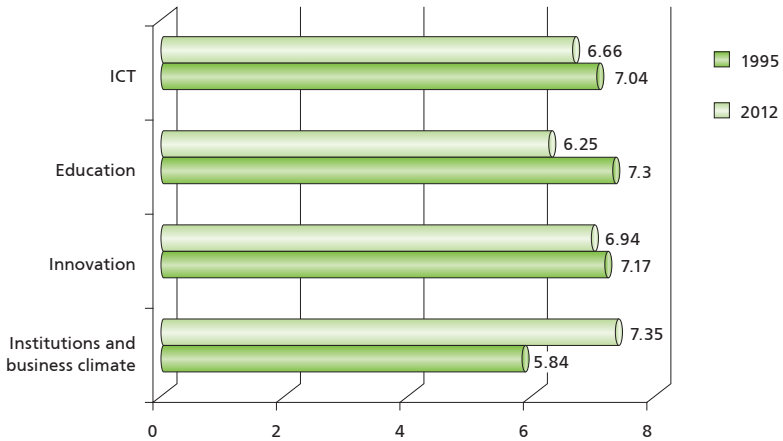
Despite Bulgaria's rock-bottom position in nearly all 25 indicators, the country still has relative strengths in human resources, intellectual assets and economic effects of innovation. There has been an annual growth of over 20 % for trademarks and R&D expenditure in the business sector. Export of innovation services, scientific co-publications of private and public partners and registration community designs have grown by 9.5 %, 12.6 % and 17.1 % respectively. These positive trends should be supported actively by an adequate state innovation policy.

Bulgaria has registered progress in respect to the **World Bank's Knowledge Economy Index**.[12] Compared to 2000, the country has climbed up by six positions in 2012, ranking 45th among 145 countries. On a comparative scale within the EU, however, the existing backwardness is exacerbated. Bulgaria ranks last in the index compared to the rest of the EU member-states. Obviously, the policies implemented in recent years in the field of education, research, technological development and innovation have proved insufficient to lead to a real positive change corresponding to the rates of development of other European economies.

In 1995 – 2012, Bulgaria made the greatest progress as regards its regulatory and legal framework, institutional environment and business environment. The World Bank findings, it should be noted, have a considerable time lag and do not reflect entirely the effect of the crisis. The situation with the indicators for innovation development, however, is different. Both with respect to innovation and to ICT the value of the knowledge economy index for Bulgaria is declining. Particularly worrying is the drop in education which further undermines the capacity of the Bulgarian economy to absorb and generate innovation.

The position of Bulgaria in the **Global Competitiveness Report 2013 – 2014** is similar: it ranks 57th among 148 countries, without significant changes over the past few years. Once again, the stable macro-environment combines with very low levels of innovation potential indicators (quality of research projects, business expenditure for R&D, interaction between universities and business in R&D). According to the findings of the Report, innovativeness is the factor least contributing to the competitiveness of the Bulgarian economy.

Figure 2. KNOWLEDGE ECONOMY INDEXES, BULGARIA, 1995 – 2012



Source: Knowledge Economy Index, World Bank, 2012.[13]

[12] Knowledge Economy Index, The World Bank, http://go.worldbank.org/JGAO5XE940

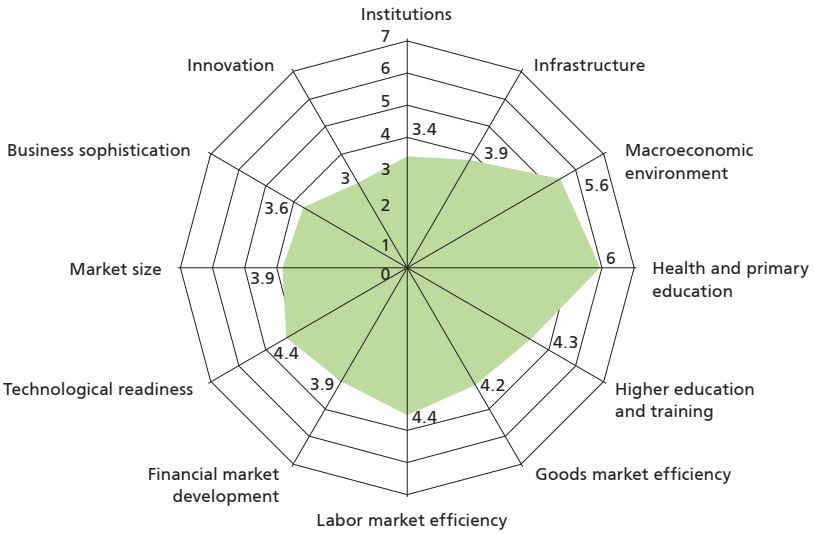
[13] http://go.worldbank.org/JGAO5XE940

The Global Competitiveness Report finds Bulgaria and Romania to be the only EU28 member-states at the so-called second stage of development, based on the improvement of economic efficiency (after the factor-driven economy stage defined as stage 1). The majority of the member-states rely on new knowledge and technologies as a source of high added value and better quality of life.[14] All other new member-states, including Croatia, are in the stage of transformation from efficiency-driven growth to innovation-driven.

The implementation of research, technological and innovation policy in Bulgaria that is inconsistent, underfinanced and is lacking purpose, reflects on the exceptionally low innovation activity of business. Without doubt, **the adoption of policy documents only under pressure from Europe, the imitation of initiative by introducing legislative measures without care for their implementation, failure to determine relevant priorities for the development of the national economy (and the science and education supporting it) cannot but result in further lagging behind of Bulgarian enterprises in comparison to their European and international partners**. Truly innovative enterprises in Bulgaria, which exist through innovation and compete on the basis of new knowledge, are a rarity. A large portion of Bulgarian business does not develop innovations or introduces new processes and products at exceedingly low innovation level, without any essential impact for the relevant company or the economy as a whole.

The latest edition[15] of the **European Innovation Scoreboard** (EIS)[16] again places Bulgaria among the group of modest innovators, along with another seven East European countries, but with a stress on the country's progress (of all 30 indicators, Bulgaria has performed worse only in R&D expenditure in the public sector as per cent of GDP and the indicators for business efficiency as result of innovation). **In addition to the negative influence of the crisis on the innovation activity of enterprises, the lack of an adequate innovation policy at the national level reflects in Bulgaria's nearly 19 % drop in the innovation index** in the

Figure 3. NATIONAL PILLARS OF COMPETITIVENESS, BULGARIA, 2013 – 2014



Source: The Global Competitiveness Report 2013 – 2014.

Table 4. STAGES OF DEVELOPMENT OF EU MEMBER-STATES

Efficiency-driven economies	Transformation from group 2 to group 3	Innovation-driven economies	
Bulgaria	Estonia	Austria	Italy
Romania	Hungary	Belgium	Ireland
	Latvia	Cyprus	Luxembourg
	Lithuania	Czech Republic	Malta
	Poland	Denmark	The Netherlands
	Slovakia	Finland	Portugal
	Croatia	France	Slovenia
		Germany	Spain
		Greece	Sweden
		United Kingdom	

Source: The Global Competitiveness Report 2013 – 2014.

[14] http://www.weforum.org/reports/global-competitiveness-report-2013-2014

[15] The pilot edition of the European Innovation Scoreboard was published in 2000. The latest 2009 report, which covers the 2006 – 2008 period, was published in 2010. After the launch of the Europe 2020 Strategy and its pilot initiative Innovation Union, launched in 2010, the European Commission continues to measure the innovation potential of member-states with the help of the renewed Innovation Union methodology, http://ec.europa.eu/enterprise/policies/innovation/facts-figures-analysis/innovation-scoreboard/index_en.htm

[16] European Innovation Scoreboard (EIS) 2009, European Commission, Enterprise and Industry, PRO INNO EUROPE PAPER N15P 2010.

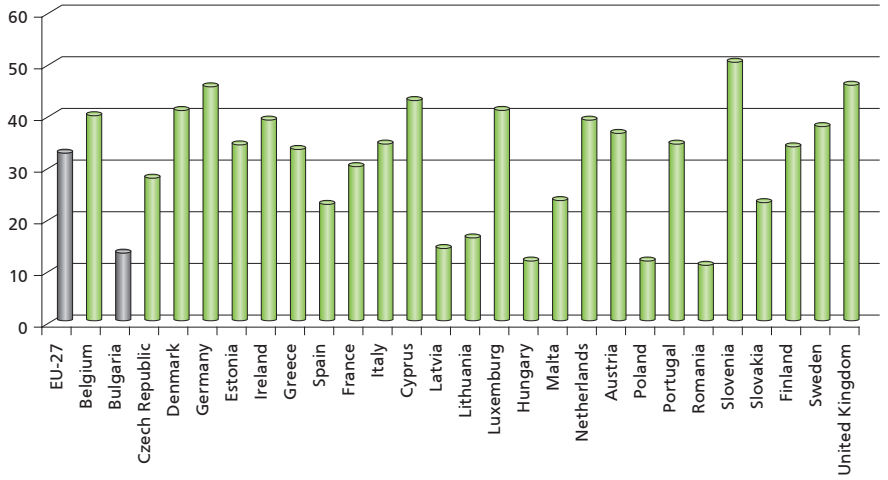
two consecutive five-year periods 2008 – 2012 as compared to 2006 – 2010 according to the Innovation Union[17] methodology, **the sharpest decline within the EU**.

The Community Innovation Survey (CIS) of innovation activity of enterprises in EU member-states for the five-year period of 2008 – 2012 established that one-third of the firms in Europe define themselves as innovative.[18] In Bulgaria, innovative enterprises amount to a mere 13 %. For yet another year, Bulgaria ranks among the last according to this indicator. Europe's innovative leaders in the period of crisis are Germany (45 % of enterprises), Cyprus (42 %), Denmark and Luxembourg (41 %), Belgium and the Netherlands (40 %). Bulgaria only ranks before Hungary (11.4 %), Poland (11.34 %) and Romania (10.75 %).

Only 3.3 % of the innovative enterprises in Bulgaria rely on external organisations (business partners, universities, R&D units) as a source of information and ideas for development of new processes and products. Only Romania (2.93 %) has a lower result according to the innovative interaction indicators. In the global economy, however, partnerships for innovation are becoming a key survival factor.

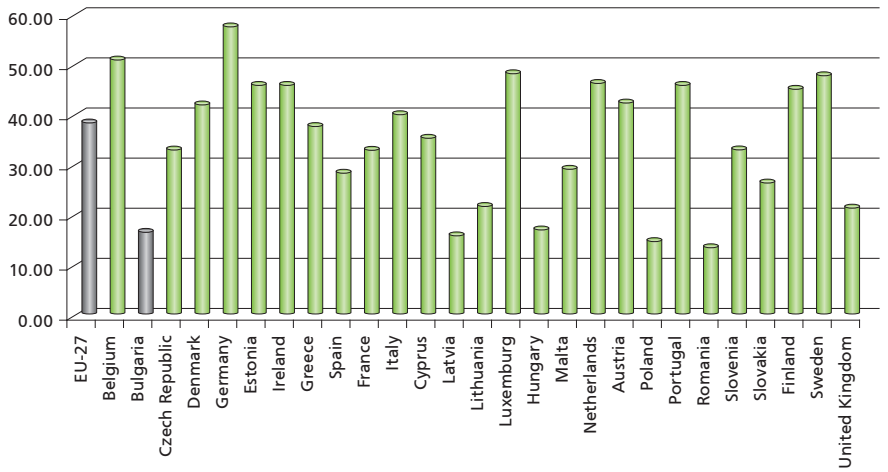
Half of the member-states registered a decline of business innovation after the lowest point of the crisis in 2010. The most drastic decline of innovation activity in enterprises was registered in Romania (-12 %). The Netherlands stands at the other end of the scale, with 9.4 % more enterprises perceiving the crisis as an opportunity and engaging in innovation as a result. The enterprises in Bulgaria which have offered a new process and/or product on the market have declined by 1.7 %, and nearly 1 % fewer enterprises registered organisational or marketing innovations.

Figure 4. ENTERPRISES WITH INNOVATION ACTIVITY, %[19]



Source: Community Innovation Survey 2008 – 2012.

Figure 5. PRODUCT/PROCESS INNOVATORS AMONG SMEs, %



Source: Community Innovation Survey 2008 – 2012.

The skill to extract the maximum effect from successfully implemented innovation projects is also a problem for Bulgarian enterprises. Increased innovation intensity (enterprise expenditure for research and innovation, growth by types of innovation activity) does not lead to more effective utilisation of materials and human resources. There is also a decline in the share of turnover from products that are new to the firm and the market.

As a whole, the national innovation system is characterised by weak innovation demand and supply. Weak domestic demand does not encourage innovations in enterprises. The export-oriented firms prefer to purchase foreign innovations. There is no trend pointing to a development

[17] http://ec.europa.eu/enterprise/policies/innovation/files/ius-2013_en.pdf

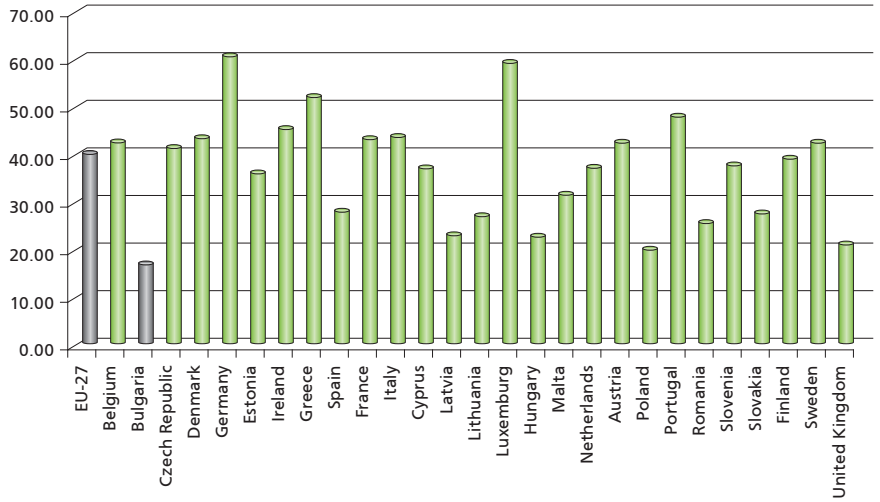
[18] http://epp.eurostat.ec.europa.eu/portal/page/portal/science_technology_innovation/data/database

[19] The data for Slovenia and the United Kingdom cover the period of 2008 – 2010.

of powerful enterprise-based science. The link between business and education is not institutionalised and thus not subordinate to a development strategy. The offering of innovations is influenced by the slow changes in R&D and university units, scarce funding and insufficient orientation of some of them towards the needs of end-users.

Foreign investments in Bulgaria do not influence the development of research-based innovations. Considering the strongly developed and cheap scientific potential of the newly-emerging markets, Bulgaria's capacity to attract such investments is limited, regardless of the favourable macroeconomic conditions.

Figure 6. ORGANISATIONAL/MARKETING INNOVATORS AMONG SMEs, %



Source: Community Innovation Survey 2008 – 2012.

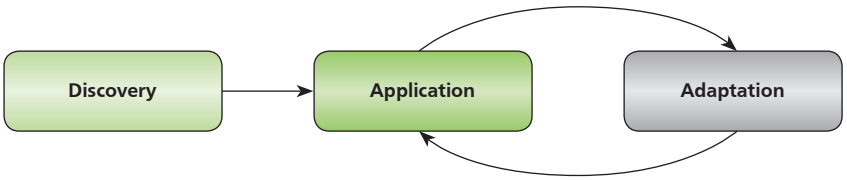
Box 2. CONCEPTUAL MODEL OF INNOVATION IN THE PUBLIC SECTOR

While innovations in the private sector have long been considered the main source of growth and competitive advantages, the public sector frequently gets neglected in debates about innovation. There is ample evidence that the capacity of governments to adapt and introduce new models, processes and services in the public sector is decisive for the overall innovation development of an innovation economy.

ARC Fund joined an international consortium of partners implementing the Complex Challenges, Innovative Cities project including 14 partners from 13 municipalities and regions in 10 EU member-countries which will identify opportunities for introducing innovations in local and regional governance, as well as innovation capacity-building of local (municipal) and regional (NUTS2 or NUTS3) administrations and other stakeholders.

Analysing nearly 100 interviews with stakeholders in the countries participating in the project, ARC Fund developed four conceptual models illustrating how innovations in the public sector at local and regional levels emerge. The models also cover the distribution – or diffusion – of innovations in public structures.

Figure 7. CONCEPTUAL MODEL OF INNOVATION – INNOVATION AS APPLICATION AND ADAPTATION OF DISCOVERY



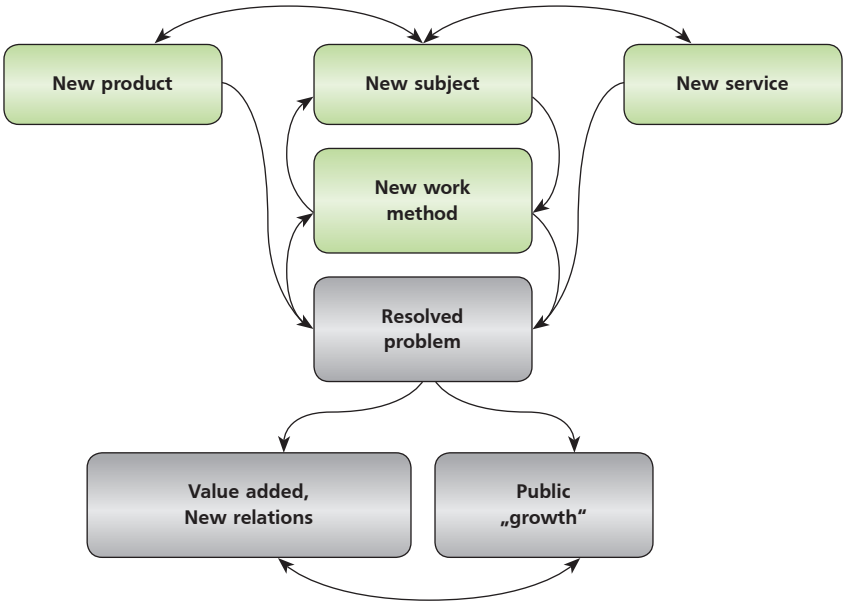
Model 1 focuses on the process of application of a 'discovery' such as, for example, a new public service. As a result of the application of the innovation, adaptation (or gradual improvement) of the initial condition takes place, which then prompts further innovations. The uninterrupted cycle of application-adaptation-application is the diffusion or distribution of the innovation in the public sector.

Model 2 involves a new product, new subject, new service or new method of work, all of these standing at the basis of the innovation process in the public sector. The combinations and interactions between these resources are those that largely contribute to the generation of a given innovation. For example, the introduction of a new subject (or policy

priority) for local or regional authorities in turn requires the introduction of a new method of work (new approach) to achieve results from the innovation. This objective may also require the introduction of a new type of service.

Usually, the resulting innovation is a resolved problem, which is also the end result of innovation in the public sector. The most important result in the public sector is the value added from the innovation, the new relations which emerge and, in the long run – the public "growth" achieved.

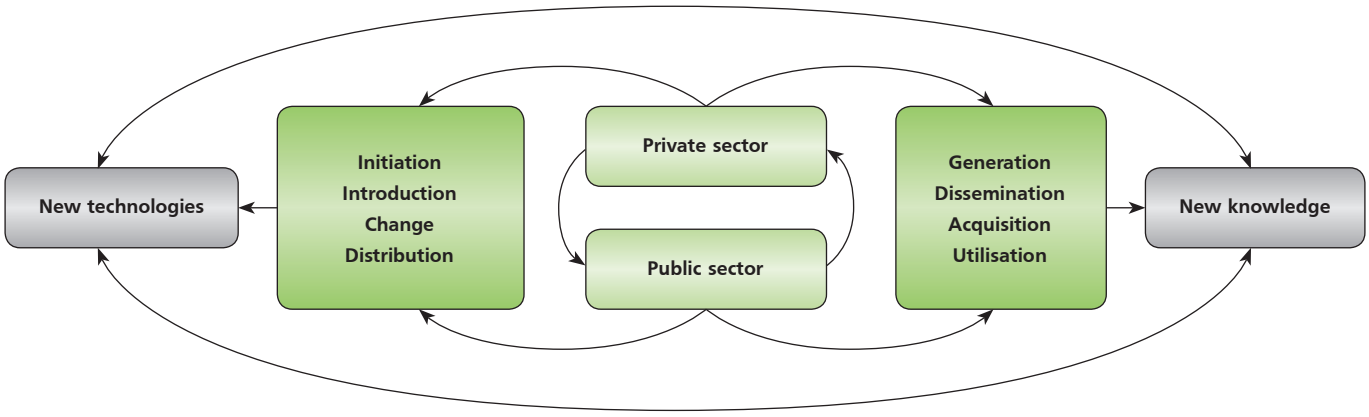
Figure 8. CONCEPTUAL MODEL OF INNOVATION – RESOLVING CHALLENGES AND ACHIEVING PUBLIC "GROWTH"



New methods of work originate with the resolution of a problem, and these in turn can lead to the introduction of new subjects and determining of new priorities, or even to the introduction of an entirely new sphere of activity in the public sector. This cycle closely corresponds to the application-adaptation-application model shown in Model 1.

Model 3 emphasises partnerships between the public and the private sector. The principal assumption of this model is that the participation of the private sector is also necessary for an innovation to appear in the public sector. Cooperation between the two sectors allows the generation of new practices.

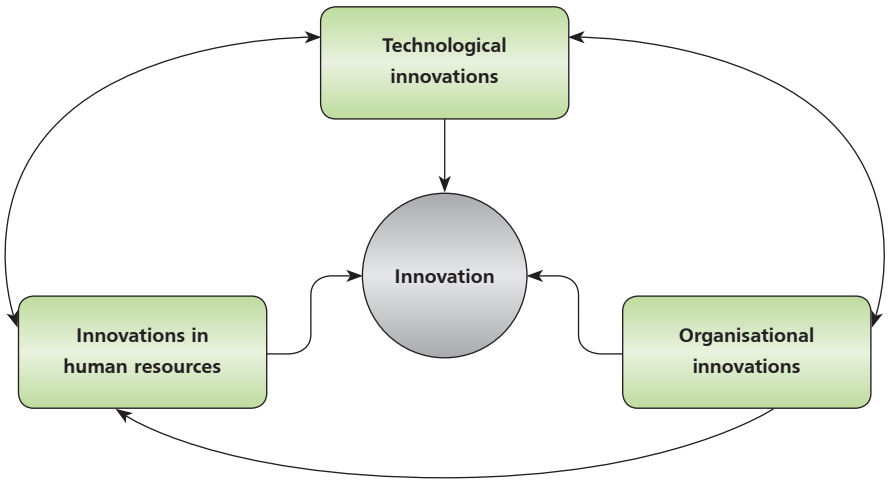
Figure 9. CONCEPTUAL MODEL OF INNOVATION – INTERACTION BETWEEN PUBLIC AND PRIVATE SECTORS



The introduction of new environment-friendly technologies in the transport sector serves as an example of this innovation model. Although they originate in the private sector, they lead to new approaches in public transport and protection of the environment, thereby effectively generating value added in the public sector.

Box 2. CONCEPTUAL MODEL OF INNOVATION IN THE PUBLIC SECTOR (CONTINUED)

Figure 10. CONCEPTUAL MODEL OF INNOVATION – COMBINATIONS AND ITERATIONS OF INNOVATIONS



Model 4, derived from interviews with the stakeholders, puts innovations in a more limited organisational context, at which innovations in the public sector originate only within the framework of public institutions. The model sees three types of innovations as resources – those related to human resources, those related to organisational management and those related to technology. It also considers innovations as the consequence of one of these innovative steps or of various combinations among them.

Source: ARC Fund, 2013.

A quest for the high-tech

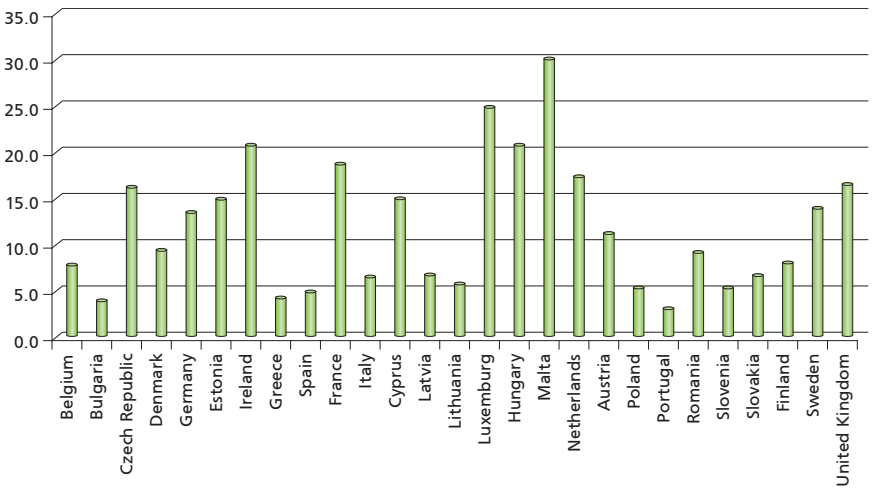
The existence of a high-tech sector and human resources engaged in R&D acquires prime importance for the attraction of foreign direct investment, including through the establishment of R&D units, and can successfully replace temporary factors such as geographical location and cheap workforce. Some new EU member-states (the Czech Republic, Slovakia, Slovenia, Hungary) successfully availed themselves of this approach and enjoy the interest of investors.

Until 2004, employment in the high-tech sectors Bulgaria declined – as did the EU average – after which it recovered somewhat. In 2007, the share of employees in sectors with high value added compared to the general employment in the country approached 80 % of the level of the indicator for EU27.

According to Eurostat data, in Bulgaria in 2010 there were 7,623 enterprises operating in the field of high-tech, a 72 % rise compared to 2000. Nearly 80 % of these offer services, 20 % is the share of industrial enterprises.

In 2011, **the high-tech sector formed 7.8 % of Bulgaria's imports (74 % per cent of which from EU member-states) and a mere 3.8 % of exports (63 % for EU member-states)**. The average EU27 levels for both indicators vary around 15 % – a share which cannot provide competitive advantage to the European economy on a global scale.

Figure 11. HIGH-TECH PRODUCT EXPORTS, % OF TOTAL EXPORTS, 2011



Source: Eurostat, 2013.

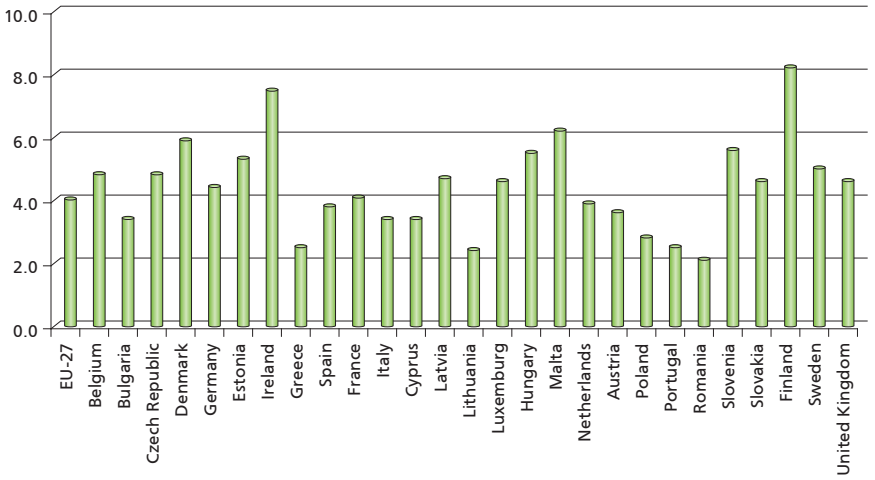
In 2011, the high-tech sector in Bulgaria provided employment to 91,000, or 3.4 % of the employed in the national economy. The average EU27 level is 4 %. Romania is the country with the lowest result by this indicator (2.1 %).

After 2000, the number of employed in the high-tech sector rose persistently. There was a decline in 2009 when the number of employed in the sector returned to the level of 2005, or a 6 % drop year-on-year. In 2011, however, this decline was compensated. In the period of intensive growth before the crisis, employment and sectoral growth were below the potential of the economy as a whole. The lack of priorities for the development of high-tech became even more clearly visible in the period of crisis, when there were no natural external motors for growth – exports, foreign investments, intensive domestic consumption, favourable credit policy.

The decline of the numbers employed in knowledge-intensive services is a worrying trend against the backdrop of the rising significance of the sector in the formation of GDP and its contribution to GVA. Along with this, this decline is evidence of diminishing efficiency in the expenditure of funds for R&D and education (which are at a quite low level to start with). In European countries, knowledge-intensive services are the economic sector which is the largest consumer of knowledge, with nearly half of those employed in knowledge-intensive services having higher education in scientific and technical fields.

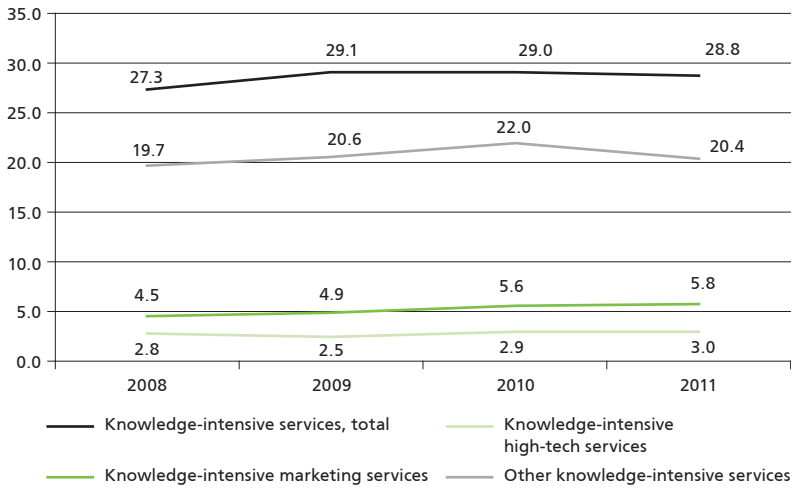
Providing the R&D sector and high-tech business in the country with the necessary human resources (in terms of number of employed and in structural terms) continues to be a challenge for the educational system and for the scientific and innovation policy providing the relevant supporting mechanisms.

Figure 12. EMPLOYMENT IN HIGH-TECH INDUSTRIAL SECTORS AS % OF TOTAL EMPLOYMENT, 2011



Source: Eurostat, 2013.

Figure 13. EMPLOYED IN KNOWLEDGE-INTENSIVE SERVICES AS % OF TOTAL EMPLOYMENT



Source: Eurostat, 2013.

Bulgaria's participation in European researcher mobility schemes offers an opportunity to overcome the existing discrepancies in the supply and effective use of human resources for technological and innovation development. Active partnership in the exchange of scientists and researchers, however, requires interesting proposals for doctoral studies and careers in priority scientific fields. A practice which is becoming increasingly popular in European countries is offering competitive grants for research with expected considerable effect for the national economy. This is usually done in areas such as nanotechnology, molecular biology, renewable energy sources, etc. – areas in which Bulgarian scientists have acquired some positions.

Overall, Bulgaria is below the average European level as regards the employed in high- and medium-tech industrial sectors. By this indicator, the

country stands at a nearly 77 % of the average level for Europe. In the case of knowledge-intensive services, the difference is even more marked – Bulgaria is only at 2/3 of the average for member-states and over twice below the level of the leading economies in Europe. In fact, Bulgaria's positions are better only compared to those of Romania.

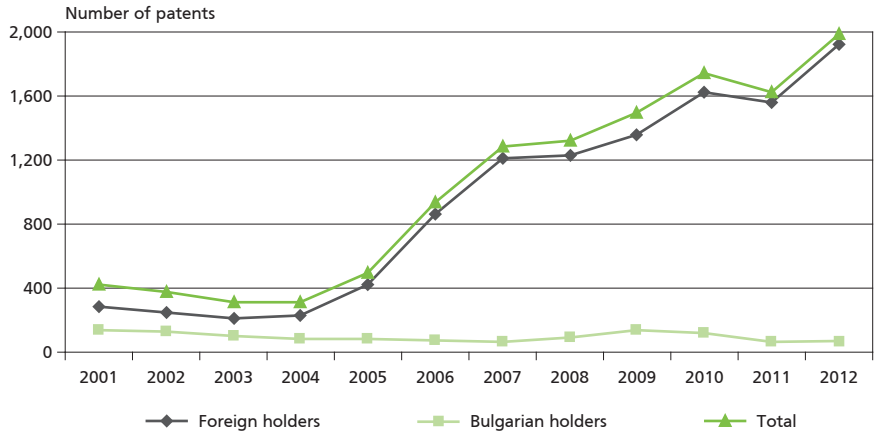
The data for 2000 – 2011 indicate a rise in absolute values of employment in the high-tech sector (high- and medium-tech industrial sectors and knowledge-intensive services). Until 2005 this trend followed the increase of employment in the economy as a whole, after which came a reverse trend of relative decline to the level of 2000 (3.09 %).

Technological Product

The technological product (protected and unprotected new technological knowledge) is a result of the creative activities of the participants in the process. Its unique characteristics and economic significance make it attractive as an object of transfer. The analysis of applicant and patent activity, as well as the attitudes of Bulgarian and foreign persons in this field make it possible to assess an essential aspect of the innovation system operation and to seek ways of improving it.

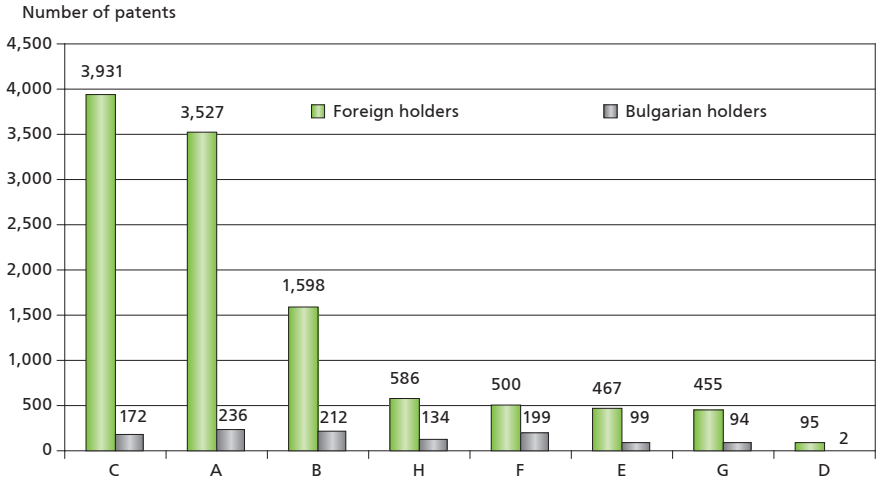
Patent-based indicators are among the most frequently used for studying the conditions and dynamics of technological development and for measuring R&D results at national, sectoral and institutional level. As an indicator of the degree and direction of technological development in the economy, patents characterise the innovation potential of a given country and its capacity to use own and foreign knowledge, and to transform them into potential economic benefit.

Figure 14. NUMBER OF PATENTS FOR INNOVATIONS ISSUED IN BULGARIA, 2001 – 2012



Source: Based on data from the Official Journal of the Bulgarian Patent Office.

Figure 15. NUMBER OF PATENTS FOR INNOVATIONS ISSUED IN BULGARIA ACCORDING TO IPC SECTIONS, 2001 – 2012[20]



Source: Based on data from the Official Journal of the Bulgarian Patent Office.

After 2000, **Bulgaria's total patent activity was influenced considerably by foreign patent presence**. In the period 2001 – 2011, 12,307 patents were issued in Bulgaria, the majority of which (90.7 %) belong to foreign patent holders, and less than one tenth to Bulgarian holders.

Of the 11,159 patents granted to foreign holders slightly over 72 % were awarded to European holders. The share of the USA within the framework of foreign patent activity stands at 18.6 %, and that of Japan – at 2.9 %. The rest of the patents (6.5 %) are distributed among 38 countries outside Europe.

Germany (2,450; 22.0 %) holds one-third of the patents of European countries in Bulgaria and slightly over

[20] **A** – Human necessities; **B** – Performing operations; Transporting; **C** – Chemistry and metallurgy; **D** – Textiles and paper; **E** – Construction; Mining; **F** – Mechanics; lighting; heating; engines and pumps; guns and ammunition; **G** – Physics.

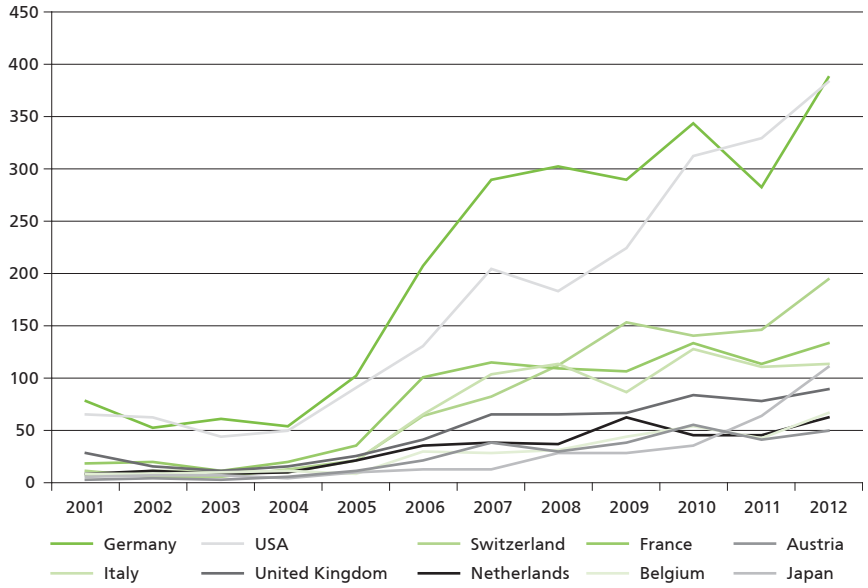
one-fifth of all patents with foreign holders, followed by the USA (2,080; 18.6 %). Representatives of nine CEE countries have also patented their innovations in Bulgaria – with a total share of 1.82 %. Of these, the highest patent activity was registered by Hungary, with a total of 89 patents for the period, two-thirds of which were granted after 2007, and holding 17th place in the ranking.

Among patents held by foreigners, **115 of all 117 technological classes of the International Patent Classification** (IPC) are represented, 23 being with less than 10 patents. Nearly 99 % of the awarded patents are concentrated in the remaining 92 classes.

Nearly half of the patents in the top 15 technological sectors are distributed quite evenly among the first two IPC classes, which far outstrip the others in terms of patent activity: C07 **organic chemistry**: general methods; acyclic, carboxyl, heterocyclic compounds; sugar; steroids; proteins – 2,875 patents with a relative share of 25.8 %, and A61 **medical or veterinary science**; hygiene; dentistry; medicinal preparations – 2,611 patents (23.4 %). Both technological classes correspond to sector **chemical industry** according to NACE.BG-2008. The patent activity in IPC class A61, which is a basis for innovation activity of enterprises from the pharmaceutical sector, is analysed in the section Innovations in Support of Sector Competitiveness below. The remaining 13 classes have shares of between 4.0 % and 1.0 %.

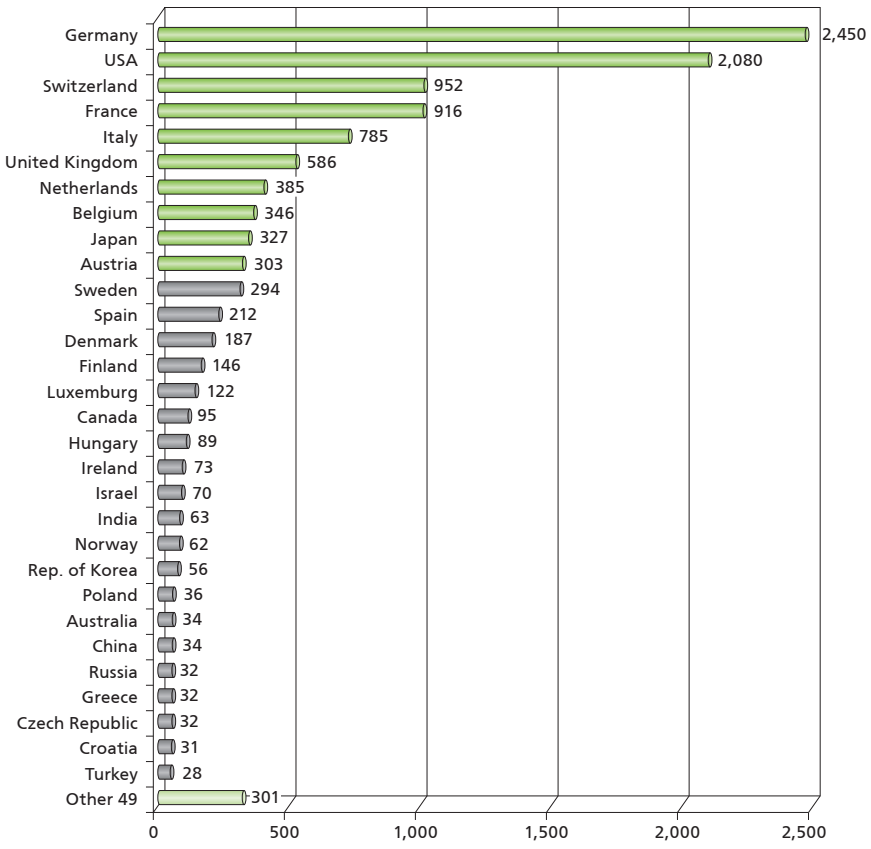
The institutional structure of Bulgarian patent holders in 2001 – 2012 reveals considerable differences by sectors. Individuals have been most active, holding 765 patents (68.3 % of the total number of patents for the 12-year period), followed by the business sector with 276 patents (23.3 %), the state sector with 89 patents (6.8 %) and the higher edu-

Figure 16. TOP 10 COUNTRIES BY THE NUMBER OF PATENTS REGISTERED IN BULGARIA, 2001 – 2012



Source: Based on data from the Official Journal of the Bulgarian Patent Office.

Figure 17. FOREIGN PATENT ACTIVITY IN BULGARIA, 2001 – 2012, NUMBER



Source: Based on data from the Official Journal of the Bulgarian Patent Office.

Table 5. TOP 10 TECHNOLOGICAL CLASSES OF FOREIGN PATENT ACTIVITY IN BULGARIA, 2001 – 2012[21]

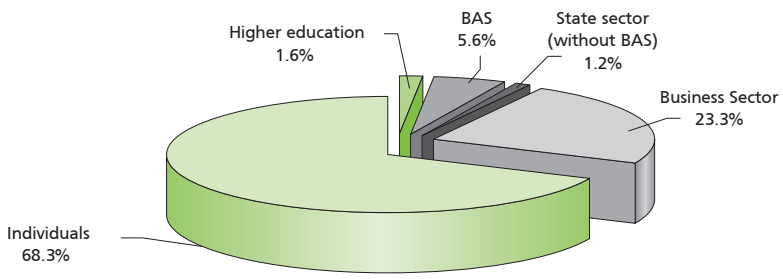
№	IPC class	Name	Patents number	%
1	C07	Organic chemistry: general methods; acyclic, carboxyl, heterocyclic compounds; sugar; steroids; proteins	2,875	25.76
2	A61	Medical or veterinary science; hygiene; dentistry; medicinal preparations	2,611	23.40
3	B65	Conveying; packing; storing	450	4.03
4	C12	Biochemistry; beer; spirits; wine; microbiology; enzymology; genetic engineering	412	3.69
5	A01	Agriculture; forestry; animal husbandry; hunting; trapping; fishing; pesticides; herbicides; disinfectants	352	3.15
6	H04	Electric communication technique; transmission; secret communication; telephonic communication; pictorial communication (e.g. TV); wireless communication networks	301	2.70
7	C08	Organic macromolecular compounds; their preparation or chemical working-up	190	1.70
8	B01	Physical or chemical processes or apparatus – dissolving, emulsifying, dispersing	172	1.54
9	H01	Basic electric elements: cables; conductors; insulators; resistors; magnets; detectors; transformers; capacitors, switching devices; resonators, etc.	166	1.49
10	A23	Foods and foodstuffs; their treatment; milk; butter; coffee; tea; chocolate; confectionery	165	1.48
11	G01	Physics – measuring; testing	163	1.46
12	E04	Building; structural elements; building materials	162	1.45
13	A47	Furniture; domestic articles or appliances; sanitary equipment	153	1.37
14	F16	Engineering elements or units; general measures for producing and maintaining effective functioning of machines or installations; thermal insulation in general	144	1,29
15	B29	Working of plastics; working of substances in a plastic state in general	116	1.04
		Total	**8,432**	**75.56**
		Other (100)	**2,727**	24.44
		Total all (115)	**11,159**	100.00

Source: Based on data from the Official Journal of the Bulgarian Patent Office.

cation sector with a mere 18 patents (1.6 %). The share of the Bulgarian Academy of Sciences (BAS) in the total number of Bulgarian patents (5.6 %) is 3.5 times larger than that of higher education. BAS holds nearly 81 % of the patents in the state sector.

The dynamics of the institutional structure of Bulgarian patent holders in Bulgaria for 2001 – 2012 involves **a declining share of individuals against increasing shares of the business and state sectors**. This trend is characteristic of the entire period under review, but has been most prominent

Figure 18. INSTITUTIONAL STRUCTURE OF BULGARIAN PATENT HOLDERS IN BULGARIA, 2001 – 2012



Source: Based on data from the Official Journal of the Bulgarian Patent Office.

[21] Георгиева, Р., Чуждестранната патентна активност в България за периода 2001 – 2012, Journal of the Technical University of Gabrovo, Vol. 45, 2013.

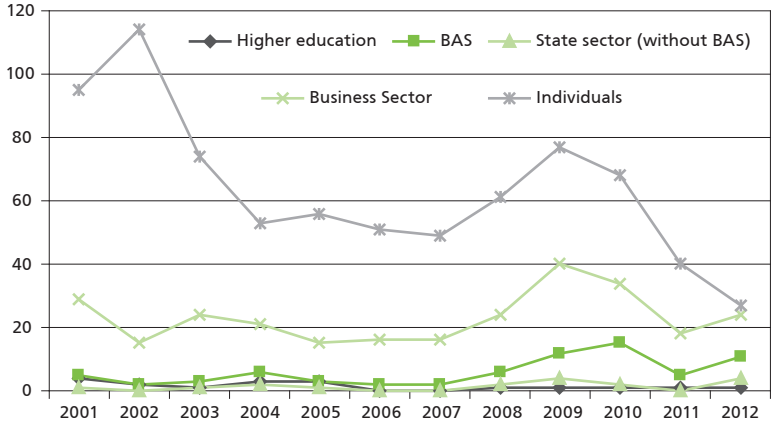
since 2010, which indicates **gradual overcoming of the low level of institutionalisation of patent activity in Bulgaria**.

The patent activity of the institutions of higher education is very weak. Just eight (of a total of 51) higher educational establishments have registered patents. The largest number (six) is held by the Medical University in Sofia and they were awarded at the beginning of the period. It is followed by the Lyuben Karavelov Higher School of Civil Engineering, Sofia, and the Technical University in Sofia with three patents each. Two patents, awarded in 2010 and 2012, are held by the Technical University in Varna. The University of Chemical Technology and Metallurgy in Sofia, the Vasil Levski National Military University in Veliko Tarnovo, the National Academy of Art in Sofia and the Faculty of Technology with the Trakia University but stationed in Yambol, are represented with one patent each.

BAS has the highest patent activity within the state sector – 80.9 % of a total of 89 patents in the sector. Most patents were registered by: **Institute of Metal Science** – 15 patents, including three patents in 2012; **Institute of Solid State Physics** – 12 patents, including two patents in 2012; **Institute for Control and System Research** – 12, including three patents in 2012 and **Space Research and Technology Institute** – 7 patents.

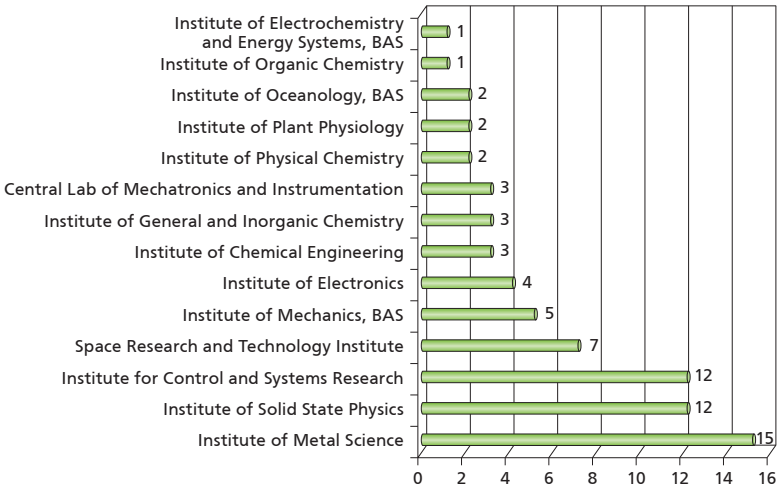
The business sector registered a total of 276 patents for 2001 – 2012, distributed in 38 cities and among 159 companies. Ten of these have registered over 3 patents each and with the total number of their patents (Top 10 = 85) account for 30.8 % of the patents of all enterprises in Bulgaria for this period. With the exception of LB Bulgaricum (number of employed 79) all patent holders are large enterprises.

Figure 19. BULGARIAN PATENT ACTIVITY IN BULGARIA BY INSTITUTIONAL SECTORS, 2001 – 2012



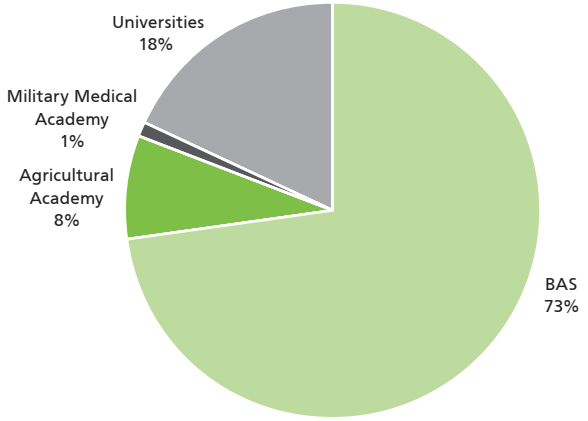
Source: Based on data from the Official Journal of the Bulgarian Patent Office.

Figure 20. PATENT ACTIVITY OF BAS, 2001 – 2012



Source: Based on data from the Official Journal of the Bulgarian Patent Office.

Figure 21. PATENT ACTIVITY OF ACADEMIC INSTITUTIONS IN BULGARIA, 2001 – 2012



Source: Based on data from the Official Journal of the Bulgarian Patent Office.

Table 6. TOP 10 BULGARIAN COMPANIES HOLDING PATENTS IN BULGARIA, 2001 – 1012

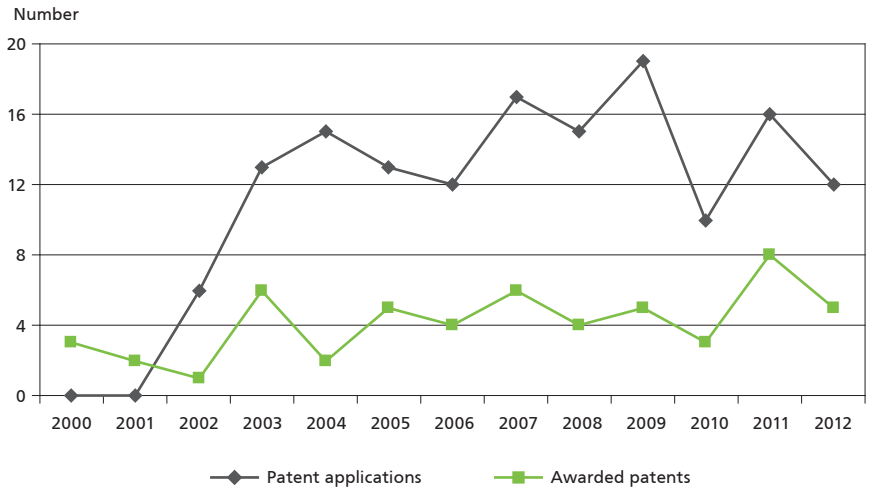
No.	Company	Location	Patents	
			number	%
1	SOPHARMA JSC	Sofia	21	7.6
2	VMZ JSC	Sopot	14	5.1
3	HYUNDAI JSC	Sofia	9	3.3
4	BIOVET JSC	Peshtera	9	3.3
5	BALKANPHARMA-DOUPNITSA JSC	Doupnitsa	7	2.5
6	BALKANPHARMA-RAZGRAD JSC	Razgrad	6	2.2
7	LACTINA OOD	Bankya	5	1.8
8	LB BULGARICUM SMJSC	Sofia	5	1.8
9	ARSENAL JSC	Kazanluk	5	1.8
10	NON-FERROUS WORKS JSC	Plovdiv	4	1.4
	Top 10 total		85	30.8
	Others (149 companies)		191	69.2
	Total all (159 companies)	**38 cities**	**276**	**100.0**

Source: Based on data from the Official Journal of the Bulgarian Patent Office.

Bulgarian applicant and patent activity before the **European Patent Office** (EPO) did not change much in the period 2000 – 2012 both as regards the filed patent applications and awarded patents. A total of 148 European applications were filed over the period and 54 European patents were awarded to Bulgarian patent holders. Bulgarian citizens still do not use to a sufficient degree the favourable opportunities for international patent activity through international applications to patent their innovations.

The patents filed with EPO are concentrated in **12 technological fields** (with five or more applications), which account for nearly half of the European patent applications. The distribution of the **European patents awarded** to Bulgarian holders by technological field includes two or more patents awarded in 11 fields and one each – in the remaining. The first three technological fields have the same number of applications and awarded patents. About 2/3 of the applications for award of patents are rejected. A case in point is the field of Civil Engineering with a total of nine patent applications and only one awarded European patent for 2000 – 2012. Such findings raise questions related to the quality of technological products created by Bulgarians.

Figure 22. BULGARIAN PATENT ACTIVITY BEFORE THE EUROPEAN PATENT OFFICE, 2000 – 2012



Source: EPO, 2013.

Bulgarian patent activity before the **United States Patent and Trademark Office** in 2000 – 2012 differs substantially from that before the European Patent Office. A total of **744 patent applications were made and 208 US patents were awarded** over the period. This is evidence of a higher interest of Bulgarian applicants in patenting their technological products and profiting from them in the USA. As in the case of the European

Table 7. TOP 5 TECHNOLOGICAL FIELDS OF BULGARIAN APPLICANT AND PATENT ACTIVITY, 2000 – 2012

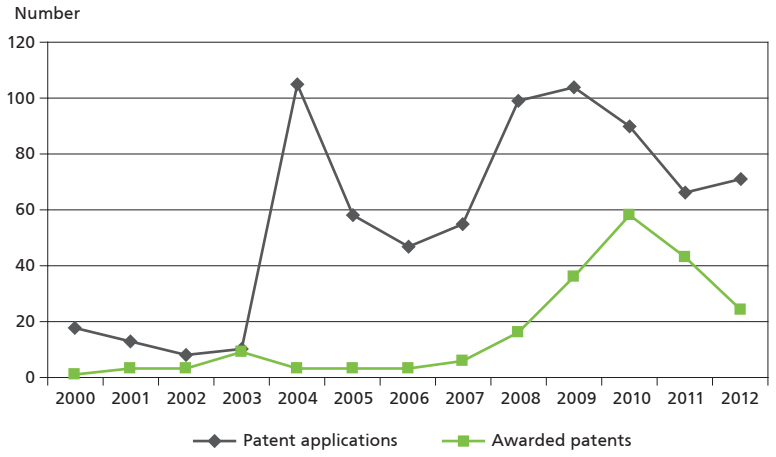
Rank	Field	Number of applications	Rank	Field	Number of awarded patents
1	Engines, pumps, turbines	14	1	Engines, pumps, turbines	5
2	Mechanics	10	2	Mechanics	5
3	Other special machines	9	3	Other special machines	4
4	Civil engineering	9	4	Pharmacy	4
5	Pharmacy	9	5	Medical equipment	3
	Top 5	51		Top 5	21
	Total	148		Total	54

Source: EPO, 2013.

Patent Office, here too the issue is the quality of patent applications – these are 3.5 times the number of awarded patents.

As to the institutional structure of Bulgarian holders of US patents, in 2000 – 2012 just about 14 % of them were individuals – inventors – while the rest were enterprises. Another typical characteristic is that 178 patents (85.6 % of all awarded) are held by persons with more than 5 patents.

Figure 23. BULGARIAN PATENT ACTIVITY BEFORE THE UNITED STATES PATENT AND TRADEMARK OFFICE, 2000 – 2012



Source: USPTO, 2013.

Table 8. BULGARIAN PATENT ACTIVITY BEFORE THE USPTO, 2008 – 2012[22]

Technological field	2008	2009	2010	2011	2012	Total
Multicomputer Data Transferring (Electrical Computers and Digital Processing Systems)	0	9	13	9	3	**34**
DP: Database and File Management or Data Structures (Data Processing)	2	9	13	4	3	**31**
DP: Software Development, Installation, and Management (Data Processing)	2	2	7	9	4	**24**
Interprogram Communication or Interprocess Communication (Ipc) (Electrical Computers and Digital Processing Systems)	0	5	6	4	2	**17**
Memory (Electrical Computers and Digital Processing Systems)	3	3	3	2	0	**11**
DP: Presentation Processing of Document, Operator Interface Processing, and Screen Saver Display Processing (Data Processing)	2	3	4	1	0	**10**
Error Detection/Correction and Fault Detection/Recovery	1	2	0	4	0	**7**

[22] Number of awarded patents by technological field according to the US Patent Classicisation.

TABLE 8. BULGARIAN PATENT ACTIVITY BEFORE THE USPTO, 2008 – 2012 (CONTINUED)

Technological field	2008	2009	2010	2011	2012	Total
Support (Electrical Computers and Digital Processing Systems)	0	1	2	2	0	**5**
Virtual Machine Task or Process Management or Task Management/ Control (Electrical Computers and Digital Processing Systems)	0	0	1	1	3	**5**
Internal-Combustion Engines	1	0	3	0	0	**4**
Other fields	5	2	6	7	9	**29**
Total	**16**	**36**	**58**	**43**	**24**	**177**

Source: USPTO, 2013.

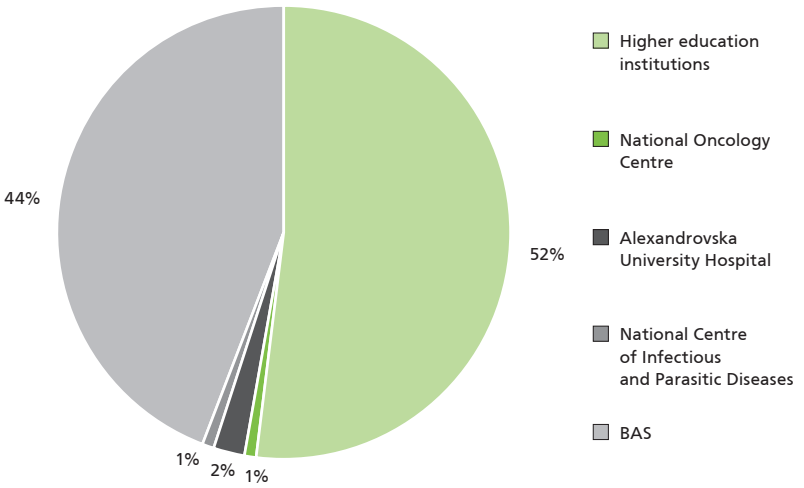
Research Product

New scientific knowledge is an important precondition for enhancing the country's innovation activity. An analysis of the dynamics and structure of this process reveals Bulgaria's potential to enter global scientific networks, the comparative advantages of the country in different fields of knowledge and its ability to compete successfully on the market of intellectual products.

Structure and dynamics of research publications

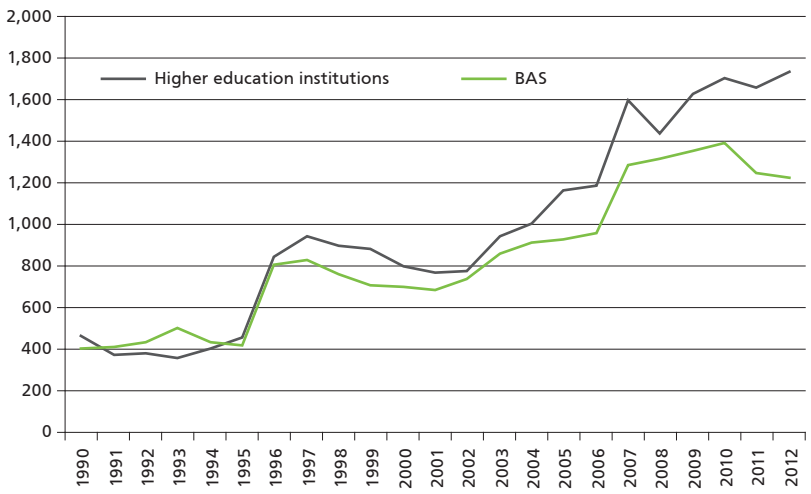
In the period 1990 – 2012, the total number of scientific papers and reports available in the Scopus reference database stood at 43,478. For most of the period, **the higher education sector retained its leading position in terms of publication activity**. Of a total of 51 higher educational institutions in the country only 17 (one-third) have published articles and scientific reports in the database. **The national research units in the field of medicine** with the Ministry of Health are quite active in publishing: the National Centre of Infectious and Parasitic Diseases with 517 publications and the National Oncology Centre (currently the Specialised Hospital for Active Treatment in Oncology, Sofia) with 296 publications, as well as Alexandrovska University Hospital with 969 publications.

FIGURE 24. SCIENTIFIC ARTICLES AND REPORTS WITH THE PARTICIPATION OF BULGARIAN SCIENTISTS IN SCOPUS, 1990 – 2012



Source: Scopus, 2013.

FIGURE 25. NUMBER OF ARTICLES AND REPORTS WITH THE PARTICIPATION OF BULGARIAN SCIENTISTS PUBLISHED IN SCOPUS REFERENCED PUBLICATIONS



Source: Scopus, 2013.

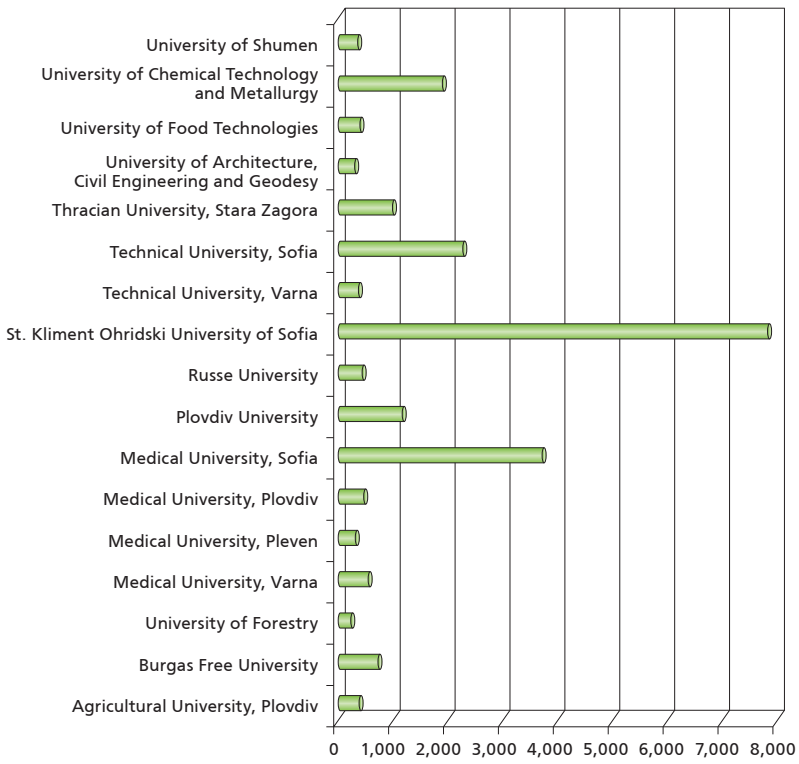
Table 9. TOP 10 SCIENTIFIC PAPERS WITH BULGARIAN PARTICIPATION BY FIELDS OF SCIENCE

Rank	Field	Number of papers	Average number of citations per paper	h-index
1	Physics	8,003	11.24	84
2	Chemistry	7,236	10.83	79
3	Materials Sciences	4,348	9.43	65
4	Engineering	3,038	8.87	58
5	Mathematics	2,369	5.91	37
6	Biochemistry and molecular biology	2,012	12.33	56
7	Optics	1,494	8.65	42
8	Pharmacology and pharmaceutics	1,361	9.96	46
9	Biotechnology and applied microbiology	1,302	6.70	37
10	Polymer Sciences	1,226	10.50	43

Source: Web of Science, Thomson Reuters, 2013.

Bulgarian scientists are represented in all 26 fields of science included in the database. **Priority fields for the country include physics and astronomy** (17 % of all publications); **chemistry** (12 %); **material science** (11 %); **biochemistry, genetics and molecular biology** (10 %); **medicine** (9 %); **engineering** (8 %). BAS (5,924 publications) and Sofia University (3,385 publications) top the ranking, followed by the Technical University in Sofia (509) and the University of Chemical Technology and Metallurgy (437). The ranking in the fields of Chemistry and Material Science is similar. **The Medical University in Sofia is among the leaders in the field of biochemistry, genetics and molecular biology** (second after BAS) and **medicine** (first with 2,080 publications ahead of BAS with 914). The Technical University in Sofia is the leader among higher educational establishments in the field of engineering with 1,053 publications (over 2/3 for the higher education sector) and ranks second to BAS on a national scale.

Figure 26. NUMBER OF ARTICLES AND REPORTS PUBLISHED BY THE HIGHER EDUCATION SECTOR IN SCOPUS REFERENCED PUBLICATIONS, 1990 – 2012



Source: Scopus, 2013.

Joint research

The academic community in Bulgaria engages in research and publishing together with research units from 144 countries worldwide. **Cooperation with academics in Germany is most intensive** (5,991 joint publications) – traditionally for Sofia University, BAS and the Medical University in Sofia. The scientific fields of mutual interest are also the leading ones for Bulgaria: physics and astronomy, chemistry, materials sciences, biochemistry, genetics and molecular biology, medicine.

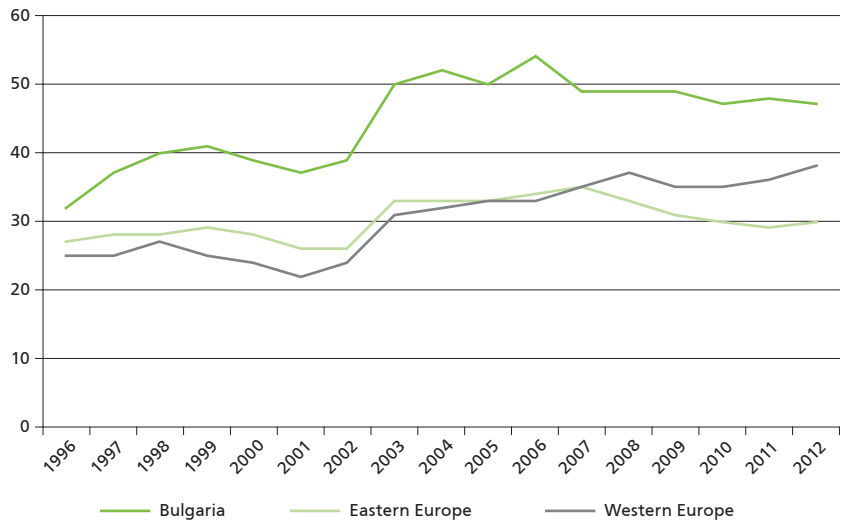
Table 10. TOP 10 BULGARIAN UNIVERSITIES BY NUMBER OF PUBLICATIONS AND CITATIONS

Rank	Higher education institution	Number of publications	Average number of citations per article	h-index
1	Sofia University	9,753	10.07	84
2	Medical University, Sofia	3,950	10.04	71
3	University of Chemical Technology and Metallurgy, Sofia	1,867	7.20	43
4	Technical University, Sofia	1,126	5.34	30
5	Plovdiv University	998	5.46	29
6	Burgas Free University	901	6.93	35
7	University of Mining and Geology	802	10.14	38
8	Thracian University, Stara Zagora	685	6.65	30
9	Medical University, Plovdiv	431	7.69	25
10	Medical University, Varna	418	7,22	25

Source: Web of Science, Thomson Reuters, 2013.

The **top 10 countries of origin of research partners** also include the USA (second with 3,872 publications), France (3,301), Italy (2,880), United Kingdom (2,600), Russia (2,187), Spain (2060), Belgium (1,709), Poland (1,701) and Switzerland (1,403). Among the countries outside Europe, the most active partnerships also include Japan (1,090), India (771) and China (688). **Among the top 5 Central European countries,** the most active cooperation after that with Poland, is registered with Hungary (1,126 or 12th in the general ranking), the Czech Republic (1,032, 15th), Romania (935, 16th) and Serbia (494, 27th).

Figure 27. SHARE OF ARTICLES IN CO-AUTHORSHIP WITH FOREIGN SCIENTISTS, %



Source: SCImago. (2007). SJR — SCImago Journal & Country Rank. Retrieved October 16, 2013, from http://www.scimagojr.com

Impact of the research product

According to the SCImago Journal & Country Rank information platform, **35 Bulgarian scientific journals are featured in the Scopus** (Elsevier B.V.) international database with a maximum h-index[23] 14 and SJR coefficient[24] up to 0.504. In comparison, the journal Nature has an h-index of 768. Among the CEE countries Poland has a publication with the highest impact factor (h-index 49 and SJR coefficient SJR 0.411).

The total number of documents included in Scopus originating from Bulgaria amounts to 45,348, 98 % of which have been cited. **The average number of citing per docu-**

[23] The scientific research impact metrics **h-index**, sometimes called the Hirsch index or Hirsch number (in the name of Californian physicist Jorge E. Hirsch who suggested it in 2005), measures both the productivity and impact of the published work of a scientist/scholar, a group of scholars or an institution. The h-index is calculated on the basis of the distribution of the citations received by most popular publications: a scholar with an index of *h* has published *h* papers each of which has been cited in other papers at least *h* times. The h-index is the only figure which corresponds to this definition. This can be done practically be recording in a descending order of lines the number of citations received by any particular publication – the h value lies there where the number of the line is larger than the number it records.

[24] The bibliometric indicator SCImago Journal Rank **(SJR)** is applied in the SCOPUS database. Like GoogleRank, SJR is an indicator which measures the prestige of annotated scientific journals on the basis of citations for a period of three years.

ment is 7.8 at a total h-index of 138, which ranks Bulgaria 50th among 238 countries. With its enormous scientific potential, the undoubted leader in the ranking is the USA (7,063,329 documents with h-index 1380), followed by China (2,680,395 documents and h-index 385). Five EU member-countries are within the top ten. Bulgaria is followed by Lithuania, Estonia, Cyprus, Latvia, Luxembourg and Malta.

Linkages between research, technological and innovation product

The haphazard, non-transparent and short term national policy in the field of science, technologies, innovations and education is among the main reasons for Bulgaria's weak performance in scientific and innovation capacity indicators in both the European Union and on a global scale. The limited financial resources for R&D and innovation, distributed in fields where no further growth is sought (in human resources through the educational system and research infrastructure at world level) and without targets like effectiveness and efficiency of public funds (with the help of indicators such as publication and patent activity, citation, new and considerably improved products and processes introduced, innovation networks established), lead to a loss of potential (outflow of human resources) and a diminished presence of the country in the international academic community.

There is a considerable discrepancy concerning the starting indicators (R&D and staff engaged in R&D expenditure) **and outcome** (publications, citations, patents) **of the national research and innovation system**. The divergence between the leading scientific fields according to funding and employment indicators, on the one hand, and the preferred educational fields, on another, is considerable. This is most clearly visible in respect to medical sciences.

TABLE 11. MAIN INDICATORS OF IMPACT OF RESEARCH PRODUCT

Rank	Country	Documents	Average number of citations	h-index
3	United Kingdom	1,918,650	18.29	851
4	Germany	1,782,920	16.16	740
6	France	1,283,370	15.6	681
8	Italy	959,688	15.26	588
9	Spain	759,811	13.89	476
14	The Netherlands	547,634	21.25	576
18	Sweden	375,891	20.11	511
19	Poland	346,611	8.25	302
21	Belgium	299,077	18.16	454
23	Austria	214,844	16.67	378
24	Denmark	208,227	21.56	427
26	Finland	190,192	18.55	372
27	Greece	180,688	12.28	266
29	Czech Republic	163,740	9.28	239
33	Portugal	138,892	13.06	234
37	Hungary	112,177	11.76	254
39	Ireland	104,634	16.47	271
41	Romania	92,264	6.34	135
47	Croatia	57,454	6.45	143
48	Slovakia	56,552	7.78	148
49	Slovenia	50,565	9.53	153
50	Bulgaria	45,348	7.8	138
59	Lithuania	24,755	8.61	109
64	Estonia	19,141	13.58	130
73	Cyprus	10,311	12.46	86
74	Latvia	10,082	8.61	85
88	Luxembourg	6,736	12.97	80
115	Malta	2,517	12.5	60

Source: SCImago. (2007). SJR — SCImago Journal & Country Rank. Retrieved October 17, 2013, http://www.scimagojr.com

Table 12. (IN)CONSISTENCY AMONG NATIONAL PRIORITIES IN THE FIELD OF SCIENCE, EDUCATION AND INNOVATION

R&D expenditure, % of total R&D expenditure, 2012	Staff engaged in R&D, % of total staff engaged in R&D, 2012	Research product, Number of publications, 1990 – 2012	Technological product, Number of patents, 2001 – 2012	Number of graduated students by field of education, 2012	Number of graduated doctoral students by field of education, 2012
Medical sciences 44 %	Technical sciences 27 %	Physics and astronomy 11,084	A – Human necessities 236	Economic sciences and administration 18,516	Social and human sciences 109
Technical sciences 24 %	Natural sciences 26 %	Chemistry 8,043	B – Technological process; Transporting 212	Social and human sciences 9204	Humanities 107
Natural sciences 19 %	Social sciences 13 %	Materials sciences 6,980	F – Mechanics; lighting; heating; engines and pumps; guns and ammunition, 199	Technical sciences and technical occupations 6,998	Technical sciences and technical occupations 103
Agricultural sciences 7 %	Agricultural sciences 13 %	Biochemistry, genetics and molecular biology 6,651	C – Chemistry and metallurgy 172	Teacher training and education sciences 3,922	Teacher training and education sciences 98
Humanities 4 %	Medical sciences 12 %	Medicine 5,815	H – Electricity 134	Health 2,989	Health 91
Social sciences 3 %	Humanities 9 %	Engineering sciences 5,108	E – Construction; mining 94	Humanities 2,601	Arts 72

Source: Scopus; NSI; Bulgarian Patent Office; ARC Fund calculations, 2013.

Entrepreneurship and Innovation Networks

Entrepreneurship is one of the binding elements of the national innovation system. It is embodied in newly-established companies and is the means of interaction and exchange of information, know-how and technologies among stakeholders in the innovation economy. Entrepreneurship is crucial for both the robustness and adaptability of the national innovation system. A spirit of enterprise and a culture of innovation should underlie the objectives of national innovation policy.

Entrepreneurship in Bulgaria

After more than 20 years of "free market" initiative, Bulgaria's economy is characterised by **low entrepreneurship as a result of the lack of confidence in the role of entrepreneurs in society and the high relative levels of adversity to economic and financial risk**.[25] Entrepreneurs are most frequently associated with hard work, but also with opulence and luxury, high social status and corruption, with the attitude to entre-

[25] Proizvoditelja na vazmozhnosti. Obrazat na predpriemacha v Balgaria, IME, 2013.

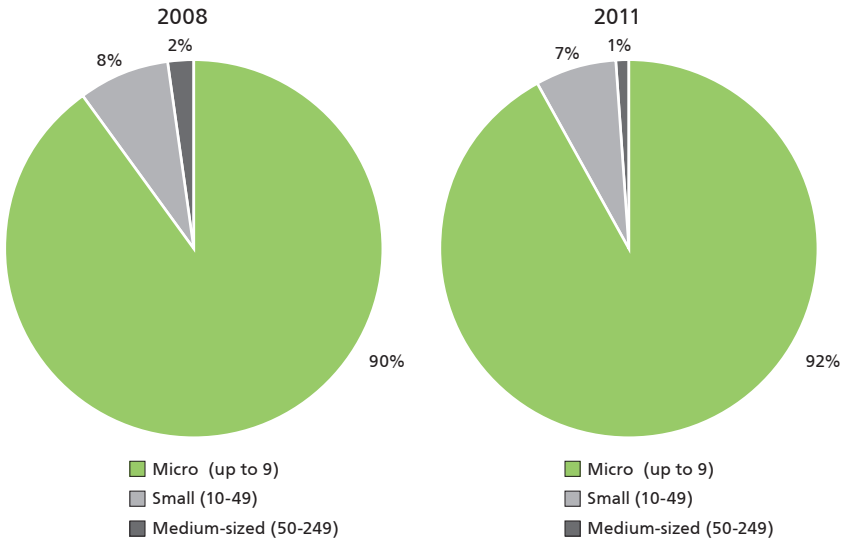
preneurship in Bulgaria having deteriorated in the last five years. Failure is regarded as resulting from a lack of appropriate skills by the entrepreneur rather than as an opportunity for a new beginning. Few people see themselves as entrepreneurs. The picture becomes rather more optimistic when it comes to young people, with a higher educational degree, living in large cities and engaged in activities with higher added value.

In the last few years, **micro-enterprises** (up to 9 employees) whose relative share was largest (336,631 enterprises, 92 %) in 2011 **continued to dominate the Bulgarian economy**. **The trend in the case of small and medium-sized enterprises is reverse, with a constant decline**, of 9 % and 17 % respectively (24,317 small and 4,536 medium-sized enterprises for 2011). **In 2008 – 2011, number of large enterprises shrank by 9** %, the only exception being 2011 (756 enterprises), when there were 4 large enterprises more compared to the previous year.

The concentration of companies in the Southwestern planning region increased, the region's leading place in terms of number of enterprises being boosted by the highest growth in the country. The total number of enterprises in the Northwestern and North Central regions declined by 1 % and 5 % respectively. Concerning the number of employees, large enterprises concentrated mostly in the Southwestern planning region (44 % of all large enterprises). SMEs are more evenly distributed around the country, although most of the enterprises are located in the metropolitan region. The number of micro-enterprises, whose relative share for 2011 is the most significant one for the economy of the Southeastern planning region (92.62 %), prevails in each of the planning regions.

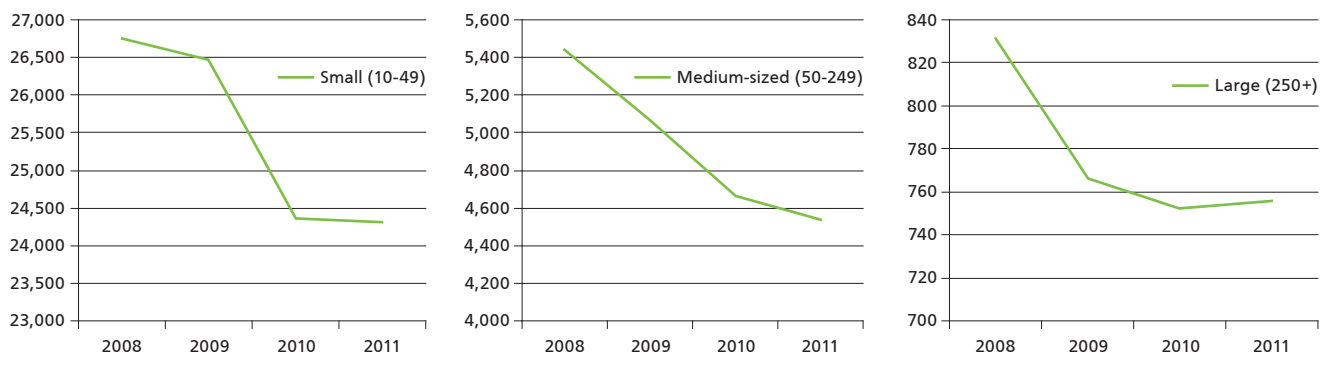
In the last five years, **the number of registered enterprises** was between 37,000 and 53,000. More significant fluctuations were observed in respect to re-registered companies. A total of 455,032 legal persons re-registered within the four-year period of 2008 – 2011 in compliance with the Commercial Register Act. The number of re-registered enterprises dropped significantly after the expiry of the 2011 deadline. After 1 January 2012, sole traders (ST) and branches of foreign traders for which re-registration was not required within this deadline or which had refusals for re-registration, were considered expunged (in case the refusal was revoked, the re-registration had to be completed by 1 June 2012). Commercial corpora-

Figure 28. STRUCTURE OF THE SME SECTOR



Source: NSI, 2013.

Figure 29. DYNAMICS OF THE NUMBER OF SMALL, MEDIUM-SIZED AND LARGE ENTERPRISES



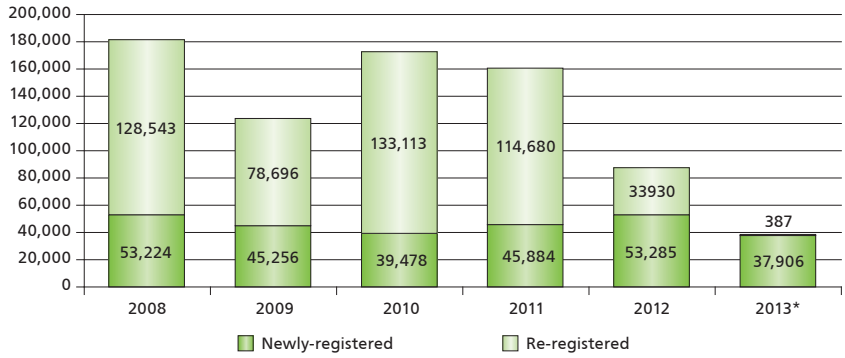
Source: NSI, 2013.

tions and cooperatives may be re-registered only in cases of a bankruptcy procedure, the application for which needs to be made to the Commercial Register by 31 January 2015. **At the beginning of October 2013, there were a total of 443,573 sole traders expunged**, 21 % of which in Sofia.

There is a continuing upward trend in the share of limited liability companies which reached 83 % in 2012 at a 1:3.3 ratio of limited liability companies (OOD) and single-owner limited liability companies (EOOD).

Most enterprises are in wholesale and retail trade and repair of motor vehicles and motorcycles (slightly over 38 % in 2011), 95 % of these being micro-enterprises with up to 9 employees. Far behind are the sectors professional activities and research (10 %, including 97 % micro-enterprises) and manufacturing (8 %, including 75 % micro-enterprises). The share of the large enterprises with over 250 employees is largest in water supply, sewage, and waste management (nearly 6 %) and mining and quarrying (slightly over 4 %). With the exception of the sector of electricity, gas, steam and air conditioning supply, where the share of large enterprises is 1.06 %, in all other sectors it is below 1 %.

Figure 30. NUMBER OF ENTERPRISES REGISTERED IN THE COMMERCIAL REGISTER



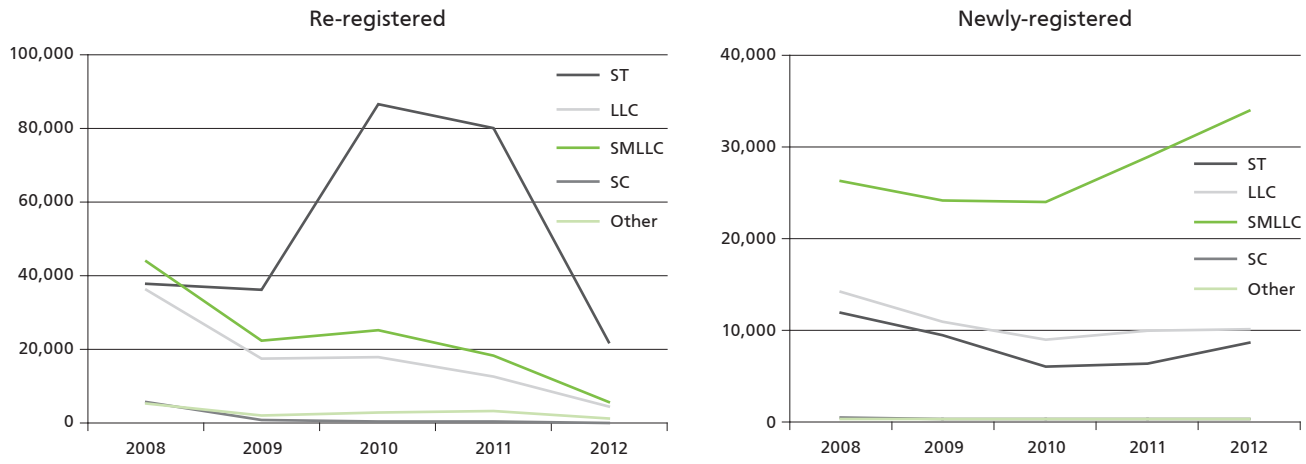
* The data for 2013 cover January-September.

Source: Registry Agency, 2013.

During the 2008 – 2011 crisis, a decline in the number of enterprises was observed only in the sector of construction – by 10 % – and in manufacturing by less than 1 %. **The total number of enterprises increased by 13 %**, the growth being entirely in 2009, with slight corrections (less than 1 %) in the next two years. The most considerable increase was registered in the number of enterprises in the sector of electricity, gas, steam and air conditioning supply (2.6-fold), followed by agriculture, forestry and fishing (70 %). In the other sectors, growth ranges between 8 and 38 %.

In spite of the increase of registered enterprises, the number of those which are active is declining, albeit by 1 % year-on-year (2009 – 2011). The most significant decline was

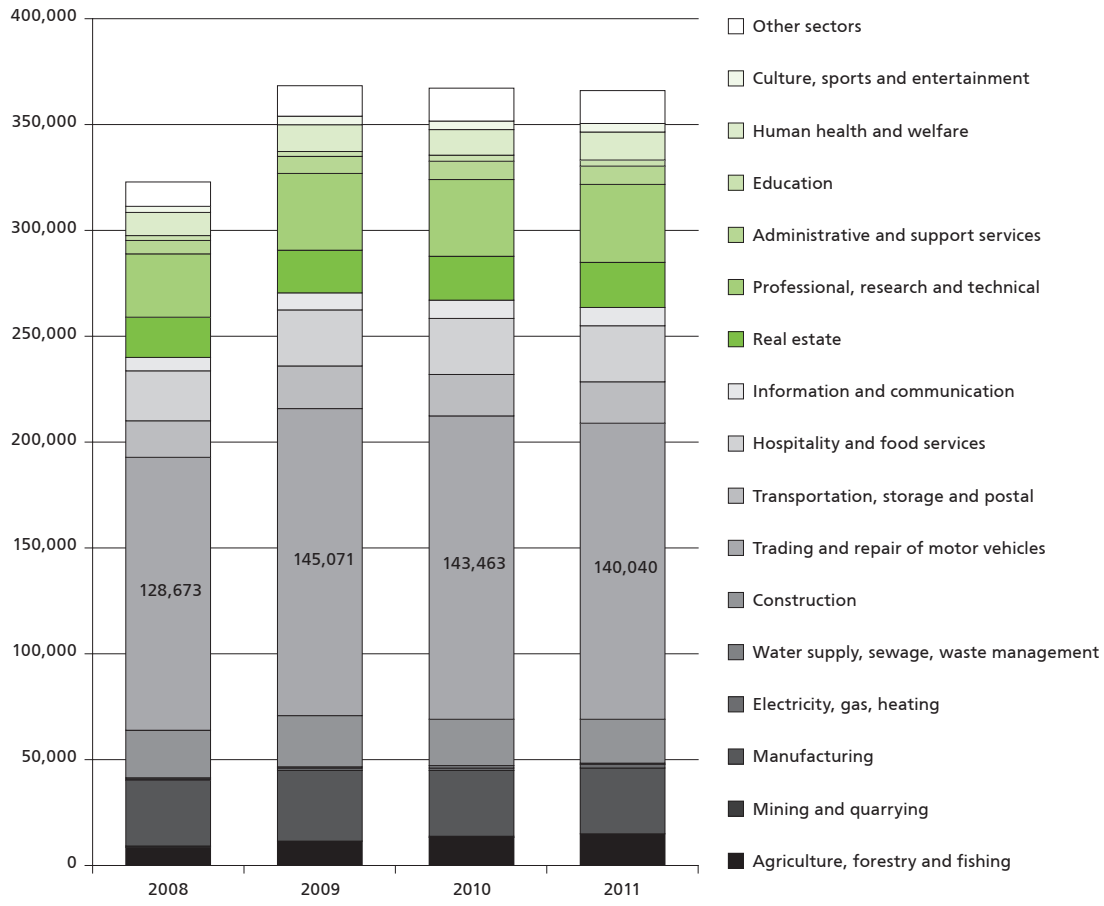
Figure 31. DYNAMICS OF ENTERPRISES REGISTERED IN THE COMMERCIAL REGISTER BY FORM OF OWNERSHIP AND BY YEAR[26]



Source: Registry Agency, 2013.

[26] ST – sole trader; LLC – limited liability company; SMLLC – single member limited liability company; SC – stock corporation.

Figure 32. NUMBER OF NON-FINANCIAL ENTERPRISES BY ECONOMIC ACTIVITIES



Source: NSI, 2013.

registered in the sector of construction (84 %), and decline was also registered in manufacturing; mining and quarrying; wholesale and retail trade and repair of motor vehicles and motorcycles; transportation and storage. **The number of newly created enterprises decreased over the three consecutive years**, their number in 2011 being slightly more than half of that in 2009. There was an even more marked decline in the number of those employed (51 %). In spite of the high "attrition rate" of enterprises in the sector of electricity, gas, steam and air conditioning supply (over two-fold in 2010 and nearly four-fold in 2011 year-on-year), the increase of newly registered and surviving enterprises compensates for the negative trend.

Intermediary infrastructure in support of innovation and technological transfer

Given the slow recovery from the financial and economic crisis of 2008 – 2009 (a 0.4 % contraction of GDP levels in the Eurozone in 2012 year-on-year) investments in science, technology and innovations are a challenge even for large economies, which additionally complicates the EU27 2020 objective of an average 3 % of GDP for R&D. National governments are being very prudent about committing public expenditure to future strategic investment priorities, preferring to prioritise fiscal stability given the pressure for austerity measures. This process is frequently accompanied by underestimation of the damage to economic growth as a result of restricted public expenditure or cancelled funding for the creation and distribution of technological knowledge.[27]

Funding allocated by main policy priorities in the EU27 has remained unchanged during 2011 – 2012. The majority of funds, in the form of grants, are still allocated to R&D, especially to:

- Research in universities (~35 %);
- Research in public research organisations (~13.5 %);

[27] Funding Research and Innovation in the EU and Beyond: Trends During 2010 – 2012, Produced under the Specific Contract for the Integration of the INNO Policy TrendChart with ERAWATCH (2011 – 2012), December 2012.

- Research infrastructures (~9.5 %);
- R&D cooperation (~8.8 %);
- Business R&D (~7.5 %).

If the size of the country is accounted for in these data, it becomes clear that **the various forms of cooperation are a priority in public expenditure for R&D with about 28 % of the entire financial resource**. This is followed by R&D in universities with a mere 11 % share of public funding. Within the public funding for an environment favouring the innovation activity of companies, European economies prioritise:

- Promotion of entrepreneurship/ start-ups (including incubators);
- Commercialisation of innovation (including IPR);
- Cooperation, promotion and clustering.

Promotion of the cooperation between science and business, including with foreign partners, is considered a condition for increasing and effective use of the innovation potential and as a factor of economic growth, which is why it is among the priorities for public support. In Bulgaria, the significance of these factors for achieving innovation growth is yet to be appreciated.

Where the environment is unstable and unpredictable, a successful business requires intensive interaction with a large number of partners and contacts. The rapid development of modern technologies and the fact that formal and informal knowledge have become the main factor of competitiveness make new rules of interaction within the innovation and industrial networks necessary – using the entire range of information exchange channels, prompt decision-making and expansion of the scope of contact groups.

Maintaining the innovation potential at a high technological level, a quickly renewable product portfolio and sustainable presence on global markets largely depend on the capacity of business to:

- Stay competent about changes in the competitive environment, and the opportunities and potential of various channels and forms of technological transfer, in order to utilise them and achieve synergic effect;
- Encourage receptiveness of knowledge generated outside the company;
- Encourage contacts and interaction within the national and international innovation networks not only within the technological chain, but also with competitive structures, university and research organsiations and intermediaries.

In Bulgaria, slightly over 92 % of the economic agents are micro-enterprises. Another 7.8 % represent the group of small and medium-sized enterprises. Given this profile of the businesses which are the intermediaries between new technological knowledge and the market in the national innovation system, **efforts must be aimed at promoting technology transfer and establishing a national framework supporting the formation of networks and close interaction between the participants in the innovation process**.

Enterprises in Bulgaria still have not developed traditions to participate in joint activity, including in innovation, and rely mainly on their own limited resources for the implementation of production process and product renewal. The companies which are active partners in innovation networks do not use the network potential to the full. **Contacts are maintained mainly within the sectoral value chain** with clients or suppliers and funding organisations. Local partners are preferred to foreign ones. **The quality of innovation networks (where such have been established) can be gauged by indicators like the small number of participants, low interaction intensity and sporadic contacts**. The lack of continual institutional exchange between the units generating new knowledge (universities, research institutes and centres), on the one hand, and business, on the other, means that there is no science-business-practice chain. The forms of transfer related to the lower levels of technological change – technical documentation, licences and models – explicably are most common on both domestic and international markets.

Within Bulgaria's national innovation system, a large number of units of

Table 13. MAIN AREAS OF PUBLIC SUPPORT IN BULGARIA, % OF PUBLIC FINANCING

	Governance and horizontal research and innovation policies	Research and technologies	Human resources	Enterprises	Markets and innovation culture
2010	75.31	21.50	1.26	1.92	0.00
2011	80.21	17.24	1.01	1.54	0.00

Source: http://ec.europa.eu/enterprise/policies/innovation/files/inno-funding-2012_en.pdf

varied status and functional identity provide intermediary services such as: dissemination of technological offers and applications, assistance for the market realisation of research findings, financial and legal consultation, information services, participation in international fora, sectoral meetings and technological broker days, etc. In spite of their large number, **intermediaries remain a weak link in the national innovation system**.

Box 3. "A NEW DIRECTION FOR HEALTH – BULGARIA"

The Cluster for Medical Tourism – Bulgaria has been in operation since March 2011 as a not-for-profit organization. With a view to institutional development and market positioning, the cluster was funded under OP Competitiveness by grant scheme BG161PO003-2.4.01 Support for Cluster Development in Bulgaria.

The main objective of the cluster is to support the development of medical tourism in Bulgaria in all its main aspects – medical, dental, SPA, etc. Initially, **the cluster began with the entire range of dental services for tourists, with other options to be added in the future** (orthopaedics, rehabilitation and SPA, dermatology and aesthetic surgery, among others), in which Bulgarian specialists can guarantee a quality competitive on a global scale. This decision for stage-by-stage development and expansion of the cluster's range of services allows it to build sustainable capacity and to avoid risks.

Cluster membership

The service provided by the cluster holistically integrates various participants – health care providers, banks, insurers, travel agents, administrative structures, among others, and is entirely export-oriented to the European and global markets, mainly Germany, UK, Ireland, Italy, the Scandinavian countries and Russia.

The members of the cluster (12 dental clinics, one travel agent and one insurer) cover all stages of the process of providing services in the medical tourism sector. Each of the clinics has an operational quality management system.

Territorial coverage

The cluster is planned to operate on the territory of the entire country. At the time of its inception, the dental clinics were located in the cities of Sofia, Plovdiv, Varna, Chepelare, Burgas, Pernik and Stara Zagora; the insurance company has headquarters in Sofia and 28 regional branches in Bulgaria; the travel agent and the advertisement company are also based in Sofia. The cluster has a policy focused on attracting new members from various places.

Opportunities for growth

Bulgaria is not present on the international map of medical tourism. In this sense, it is important to undertake measures which will build the prestige of clinics in this country and will show that they are at world level.

Bulgaria has enormous potential for growth in this niche for several reasons: 1 % of revenue in the EU is generated by health care services (approximately EUR 1 billion), EU citizens can choose freely where to be treated within the Union, reimbursement by the relevant health insurance funds is extremely easy and 48 % of the people who travel for medical treatment do so because the prices are competitive.

Hungary is a leader in dental tourism holding about 14 % of the world's market of this service. A Department of Health Tourism has been established at the Turkish Ministry of Health which connects all foreign citizens in need of treatment with a national association of clinics.

Source: Cluster for Health Tourism – Bulgaria, 2013.

Investment and Financing for Innovation

Spending on R&D and innovation is a measure of the investment in the creation, use and dissemination of new knowledge in the public and business sectors. It is an indirect indicator of the innovation capacity of national economies. High R&D intensity as proportion of GDP is a factor fostering dynamic economic growth and competitiveness.

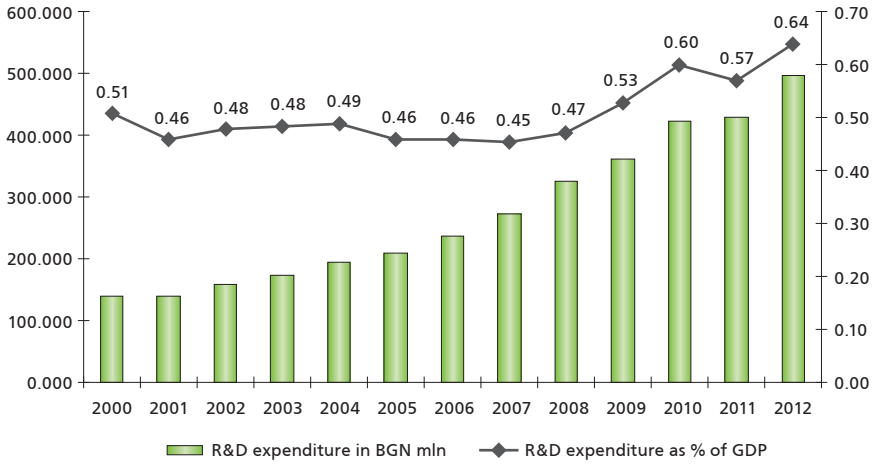
R&D Expenditure

With the draft Innovation Strategy for Smart Specialisation 2014 – 2020 developed by MEE Bulgaria confirmed its intention to achieve **increased R&D expenditure which is to reach 1.5 % of GDP by 2020** – a national objective declared with the adoption of the National Reform Programme 2011 – 2015 which, in turn, was drafted in response to the Europe 2020 Strategy and in compliance with the new tool for better coordination of economic policies within the European Union, the so-called European Semester. Contrary to expectations, **the adoption of the ambitious objective was not followed by appropriate action to increase public expenditure for research and to support business in the implementation of innovation projects**.

During the economic crisis Bulgarian governments concentrated on providing short-term financial stability and disregarded the measures oriented towards the establishment of national sources of unique competitive advantages and sustainable economic growth based on new technologies and high-quality human resources. The result is **a small share of GDP in R&D investments (0.57 % for 2012), mainly the result of foreign sources. Without the latter, R&D expenditure by all institutional sectors in Bulgaria would shrink to 0.32 % and 0.34 % of GDP respectively for 2011 and 2012**.

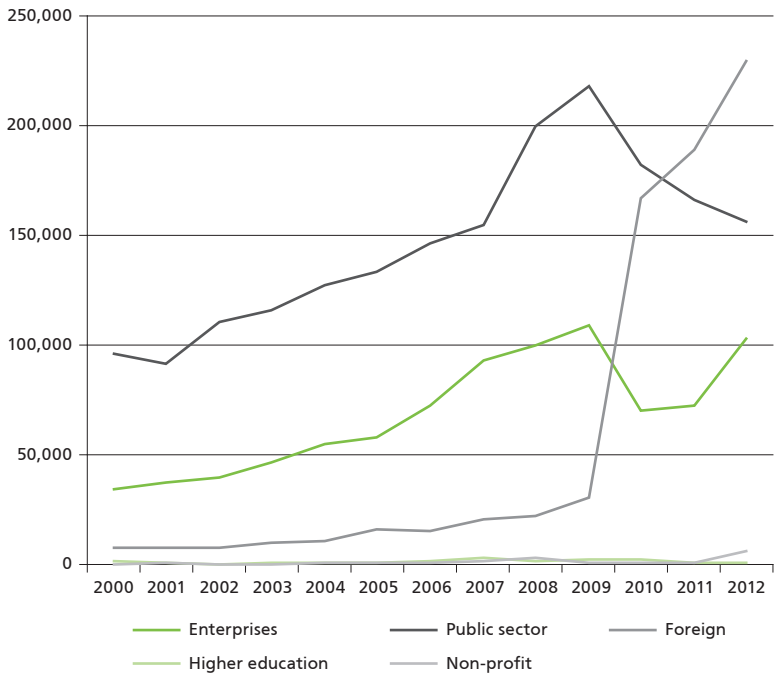
In 2012, there was **a considerable increase in business investment in R&D** (in the form of co-funding under European programmes). **The decline in public expenditure continued by** over 6 % year-on-year after the drop of 9 % and 17 % respectively for 2011 and 2010, compared to the peak val-

Figure 33. R&D EXPENDITURE IN BULGARIA



Source: NSI, 2013.

Figure 34. R&D EXPENDITURE BY INSTITUTIONAL SECTOR, BGN THOUSANDS



Source: NSI, 2013.

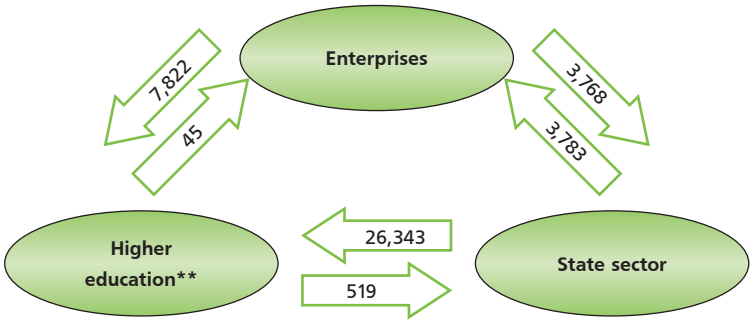
ues of 2009. There was a **sharp reduction – nearly 60 % – of the funds set aside by higher education institutions for research** during the last two years of the period.

Given the malpractices in the spending of public funds for science, the short period for planning and financial support of academic and university budgets for R&D, and the continuing deterioration of quality in the education sector, the **decline in Bulgaria's performance on the Innovation Union Scoreboard (IUS) – the sharpest in the EU – should have been expected**. Along with the deteriorating indicators for R&D funding, the country also took a step back in innovation cooperation.

Slightly less than 80 % of the funds intended for R&D by business are for research and innovation projects implemented within the enterprises themselves. Ten percent of the business expenditure for R&D goes to fund projects implemented jointly with higher educational establishments and the same share for projects with budget-funded research units (mainly BAS). In 2012, procurement by enterprises of research work from BAS dropped twofold in terms of funding. The increase of investments by enterprises in R&D implemented by higher education institutions was minimal.

Within EU28, the bulk (nearly 95 % for 2010) of the R&D funds of enterprises did not leave the business sector. Bulgaria was one of the few states in which enterprise R&D resources funded in the remaining institutional sectors (19 % for 2010 of R&D expenditure coming from sector Enterprises). Countries with a higher share included Lithuania (33 %), Romania (26 %) and Latvia (21 %).[28] In Europe's innovation leaders (Sweden, Germany, Denmark and Finland) companies maintained high levels of interaction (within the business sector) with partners, competi-

Figure 35. R&D RELATED TRANSFERS BETWEEN INSTITUTIONAL SECTORS WITHIN THE NATIONAL INNOVATION SYSTEM, BGN THOUSANDS*

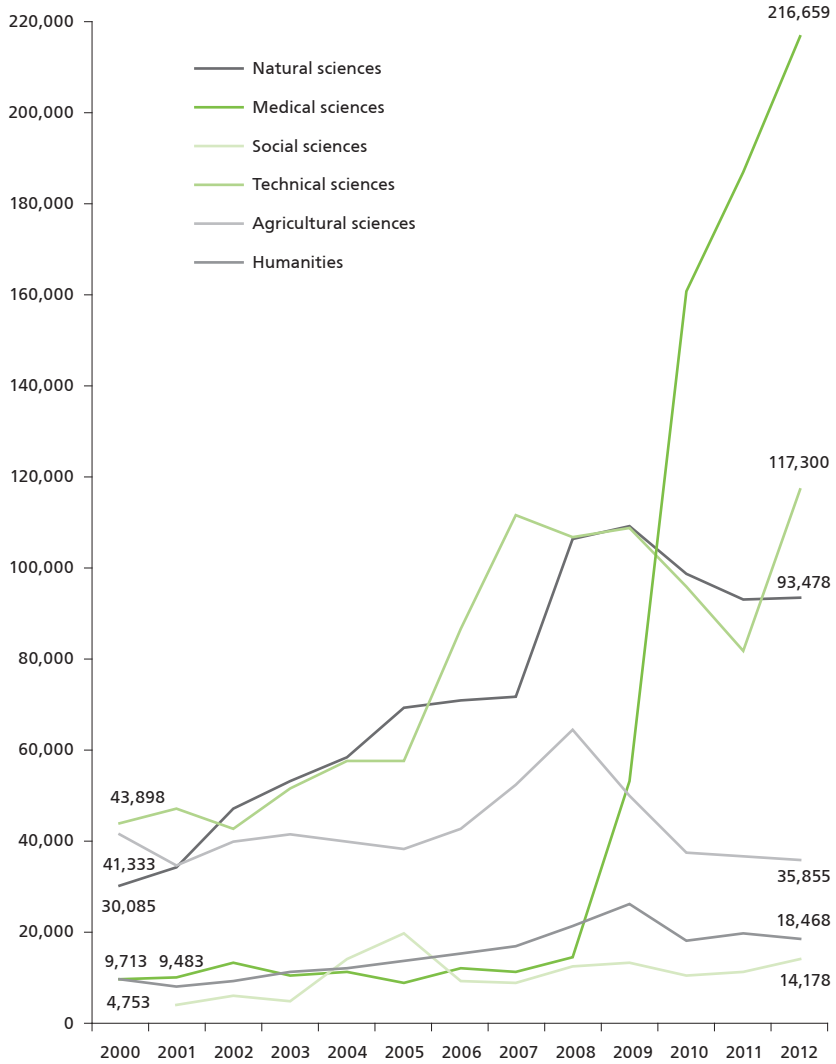


* No data available for non-profit organisations

** Data for transfers from the higher education sector are for 2011.

Source: NSI, 2013.

Figure 36. EXPENDITURE FOR R&D BY SCIENCE FIELD, BGN THOUSANDS



Source: NSI, 2013.

[28] http://epp.eurostat.ec.europa.eu/portal/page/portal/science_technology_innovation/data/database

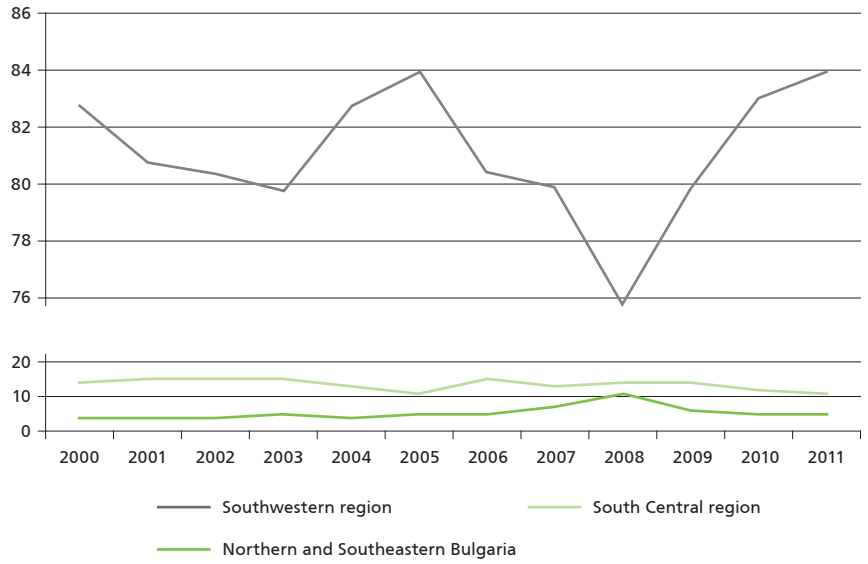
tors in the same economic sector or organisations involved in their technological chain.

The distribution of expenditure for R&D **by scientific field** shows **considerable fluctuations in time and discrepancies among the priorities of the institutional sectors**. The negligible increase of funding for natural sciences (mathematics, mechanics, physics, chemistry, biology, geology, geography) which lie at the basis of the new multidisciplinary trend in science and practice (nanotechnologies, genetics, new materials, ICT and others) and in respect to which the EU, including Bulgaria, is trying to generate competitive advantages, fails to compensate for the decline from 2009.

The situation with **budget expenditure for R&D by social and economic objectives** is similar. The radical change of priorities from one year to the next is indicative of the lack of long-term vision not only in respect to the development of fields like science, technologies and innovations, but also at the design of measures and instruments for their support.

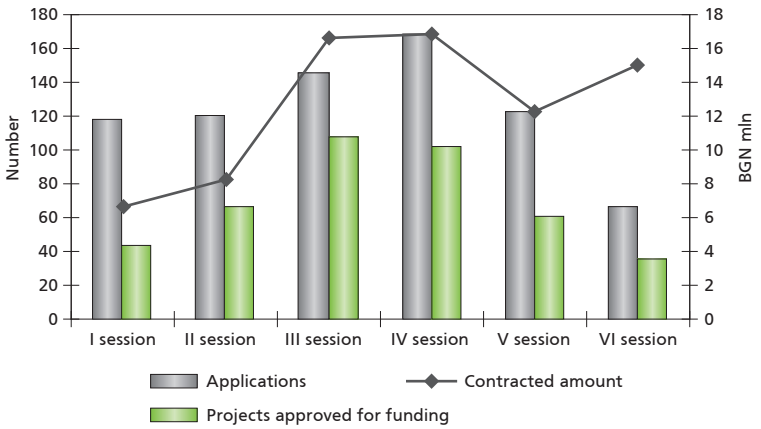
The distribution of expenditure for R&D by geographic region was quite unfavourable and continued to deteriorate at the end of the period under consideration. The lack of regional dimension in innovation policies is evident in the growing concentration of funds for R&D in the Southwestern planning region.

Figure 37. TOTAL INTRAMURAL R&D EXPENDITURE (GERD) BY REGIONS, %



Source: NSI, 2013.

Figure 38. NATIONAL INNOVATION FUND



Source: BSMEPA, 2013.

Funding of R&D in the business enterprises

The National Innovation Fund (NIF) became operational in 2005 through a Decision of the Council of Ministers in execution of Measure 1 of the Innovation Strategy of the Republic of Bulgaria. The Fund is intended to promote the implementation of scientific and research and development projects and projects for technical feasibility aimed at acquiring new or improved products, processes or services designed to enhance the efficiency, improve the innovative potential and technological level of enterprises.

The sixth call for proposals of NIF was announced on 1 October 2012. Sixty-seven project proposals were received with an overall requested amount of about BGN 18 million. Fifty-five projects requesting a total of BGN 15 million were approved for assessment by the Evaluation Committee following an administrative check of the documentation and in compliance with the Rules for management of the resources of the National Innovation Fund. Thirty-six projects were approved for funding and contracts for them were concluded by 15 December 2012.

In structural terms, the Southwestern planning region is the leading one for the country in terms of number of projects funded by NIF with 62 % for all sessions since the Fund became operational and peak values of

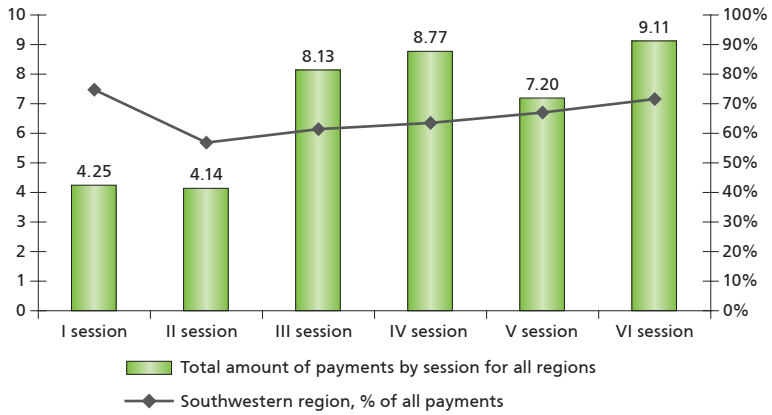
67 % at the latest sixth session. This is followed by the South Central and the North Central planning regions with 12 % and 11 % respectively. The Southwestern planning region had the smallest number of funded projects in the third session, with a relative share of 44 %. **The dominant position of the Southwestern planning region is even more visible in terms of the amounts received**. The beneficiaries from the region have contracted a total of BGN 27,450,749 for all sessions which is 66 % of the funding provided. The South Central and the North Central planning regions ranked second and third with 12 % and 9 % respectively.

Participation in the first session of the Fund was particularly active. With the exception of the sixth session, the ratio of terminated to approved projects was lowest in the first session (7 %) and reached maximum values of 28 % for the third session. On average, proposals were 82 % successful.

With its launch the NIF succeeded in attracting SME interest for funding R&D. Problems related to its functioning most frequently involve cumbersome administrative procedures for project implementation and accounting, as well as doubts about the lack of transparency at the selection process. Possible solutions can be sought in the following directions:

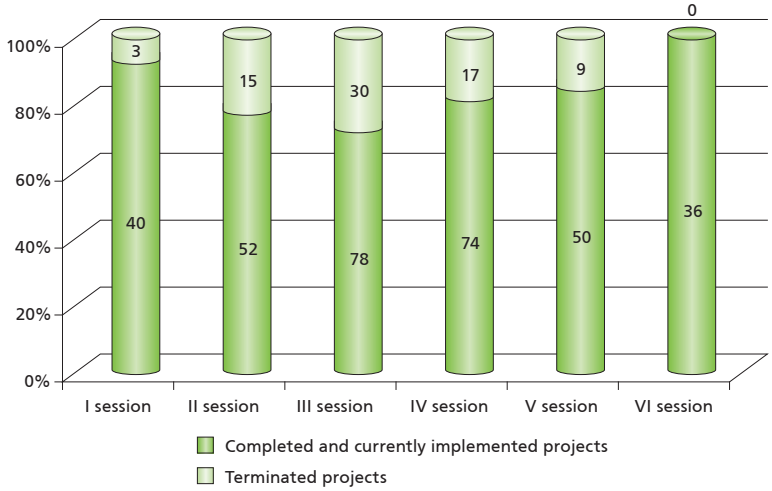
- Restructuring the Fund and its separation as an independent legal person. This would allow flexible fund management, avoidance of complicated administrative procedures and utilisation of the fund as a principal tool in the co-funding of European programmes. This can be done following the model of National Science Fund and the facility for co-funding of FP7 approved projects.
- NIF rules need to be improved. It is not expedient for technical and economic (feasibility) studies to be evaluated by the same methodology and criteria as those for applied science research projects.
- The criteria for evaluating the economic return potential of projects should be made more precise. The Fund finances research to pre-market stages but awards identical weight to innovation and economic return.
- The general management of the Fund should be improved, with the period of session planning being extended to up to and over three years. It would be appropriate to evaluate the results achieved by already completed projects and to make a general assessment of NIF efficiency.

Figure 39. NIF FUNDING BY SESSION AND SHARE OF THE SOUTHWESTERN PLANNING REGION, BGN MLN AND %



Source: MEE, 2013.

Figure 40. DYNAMICS OF NIF APPROVED PROJECTS BY SESSION, NUMBER



Source: MEE, 2013.

Bulgaria's participation in the Seventh Framework Programme

The main objective of EU's Seventh Framework Programme for Research (FP7) (2007 – 2013) was to turn the Union into a leading player on the global stage in the field of research. FP7 builds on what has been achieved in respect to the European Research Area and supports knowledge-based economy and society in compliance with the Lisbon Strategy.

As of March 2013, in a total of 381 open calls for participation under FP7 **project proposals with Bulgarian participation numbered 2,811, or 0.86 % within EU27** with a total value of EUR 804.6 million (0.53 %). For the entire period of action of FP7, 465 projects with Bulgarian participants were approved for funding with a total of 589 participants from Bulgaria and grants under the Framework Programme totalling EUR 82.73 million.

A total of 441 projects were contracted involving 6,683 participants, including 585 from Bulgaria. The overall contracted amount stood at EUR 1,510.45 million, EUR **78.52 million of which for the Bulgarian participants**.

The number of Bulgarian SMEs which applied to FP7 was 1,220, the proposals of 183 of which were approved for funding. **Forty-two Bulgarian researchers had successful projects under Marie Curie Actions** with a total budget of EUR 6.65 million.

Table 14. MAIN INDICATORS OF BULGARIA'S PARTICIPATION IN FP7

Indicator	Share within EU27	Rank in EU27
Number of applicants (% of EU27)	0.86 %	20
Declared funding (% of EU27)	0.53 %	20
Number of successful applicants (% of EU27)	16.50 % (EU=21.00 %)	23
Successful projects (% of EU27)	16.50 %	
Approved funding (% of EU27)	10.30 % (EU=19.40 %)	26
Number of participants in contracted projects (% of EU27)	0.67 %	20
Contracted funding (% of EU27)	0.27 %	21
SME success rate (% of EU27)	15.00 % (EU=20.00 %)	
Grant for SMEs (% of EU27)	11.99 % (EU=19.69 %)	

Source: DG Research and Innovation, European Commission, 2013.

Box 4. THE POTENTIAL OF BULGARIA FOR FUTURE SUCCESSFUL PARTICIPATION IN EUROPEAN FRAMEWORK PROGRAMMES

As a whole, participation in framework programmes – including success rates – is determined by the number of researchers within the respective national innovation system. **Five of the EU10 CEE member-states (Bulgaria, Estonia, Hungary, Latvia and Slovenia) had some of the highest success rates given the existing human resources in the field of research**. On average for the EU10, 20 participations per 1,000 researchers were registered, which was slightly below the level for EU27 (22 participants). In the EU10 countries the number of researchers is 245 per 100,000 of the population, while in the case of EU15 this ratio is 560 per 100,000. **The new member countries have enormous potential to improve their participation in European framework programmes and to increase their funding provided they implement a sustainable policy on generation and attraction of quality human resources in science**.

Table 15. BULGARIA IN FP7, 2007 – 2012

	Years of the period							Success rate, %	
	2007	2008	2009	2010	2011	2012	Total	2012	07-12
Number of participants in successful projects	161	94	92	90	106	42	585	11.0	16.4
European funding under successful projects (EUR mln)	18.7	11.8	14.8	13.2	13.3	10.6	82.5	7.7	10.3

Bulgaria's rankings in terms of participation in FP7 projects are as follows:

- **16th within EU27 in the ratio of successful projects under FP7 to number of researchers weighted by overall population;**

Box 4. THE POTENTIAL OF BULGARIA FOR FUTURE SUCCESSFUL PARTICIPATION IN EUROPEAN FRAMEWORK PROGRAMMES (CONTINUED)

- **5th according to successful projects to GDP ratio;**
- **3rd according to successful projects to expenditure for R&D ratio**.

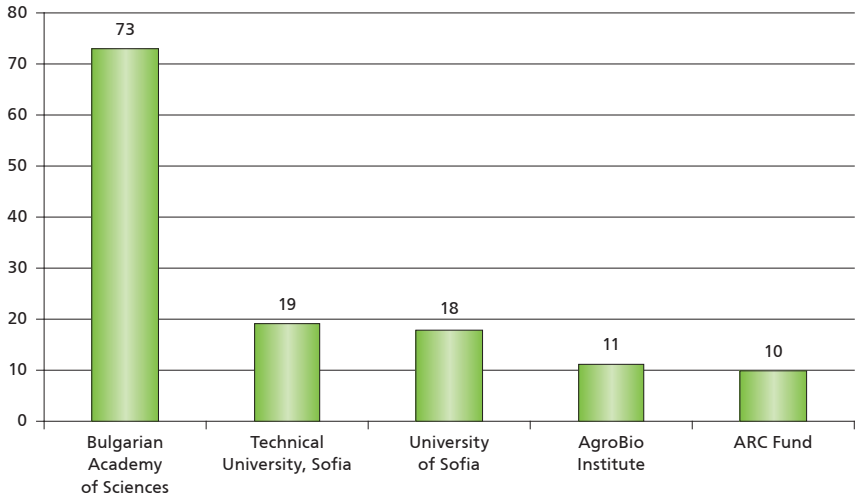
Given the correlation between the amount of expenditure for R&D as a per cent of GDP and the number of staff engaged in R&D, on the one hand, and the success rate and received funding under European framework programmes, on the other, the conclusions about the national policy in the field of science and technological development are clear: **even a minimum increase of the resources – financial and human – for research can unlock even more successful participation of Bulgaria in European and international projects for generation and exchange of knowledge**. The effect is multiplied: the larger the number of participations/coordinations of international projects a country – respectively an institution – has, the higher success rate it achieves in the future as a result of the accumulated research and project experience, know-how and contacts.

This should be accompanied by the introduction of a functioning system for regular monitoring and evaluation of the participation of Bulgarian institutions in EU framework programmes, SWOT analysis and search for opportunities for comprehensive utilisation of the existing potential.

Source: Sixth FP7 Monitoring Report, Monitoring Report 2012, 7 August 2013, European Commission, Directorate-General for Research and Innovation.[29]

In terms of the institutions participating in FP7, the leading role is that of higher education institutions (32 %), followed by research units (26 %), businesses (22 %), public organisations (about 10 %) and other organisations with the same share. In the higher education sector, the Technical University in Sofia (19 approved projects) and St. Kliment Ohridski University of Sofia (18 approved projects) rank respectively first and second. BAS with all its institutes is the Bulgarian institution with the largest number of approved projects – 73. The picture at the European level is similar – higher education institutions get most funding under FP7 (45 %), followed by research organisations.

Figure 41. THE FIVE MOST SUCCESSFUL INSTITUTIONS AWARDED PROJECTS UNDER FP7, 2007 – 2012



Source: Ministry of Education and Science, 2013.

As with R&D expenditure, participation in projects funded under FP7 reveals is very unevenly distributed around the country. Approved projects are almost entirely concentrated in the Southwestern planning region (over 70 %, 442 projects). In the other cities, most projects were approved for organisations in Varna (49), followed by Plovdiv (38), Rousse (19) and Stara Zagora (8), mainly because of universities situated on their territory.

In terms of the specific FP7 programmes, the largest number of Bulgarian participants was in Cooperation projects (52 %), followed by Capacities (29 %) and People (about 20 %); there has been no Bulgarian participation in Ideas.

Although participation in EU framework programmes is only part of the activities within the national innovation systems it is indicative of the relation between the achievements of a country, including economic

[29] http://ec.europa.eu/research/evaluations/pdf/archive/fp7_monitoring_reports/6th_fp7_monitoring_report.pdf#view=fit&pagemode=none

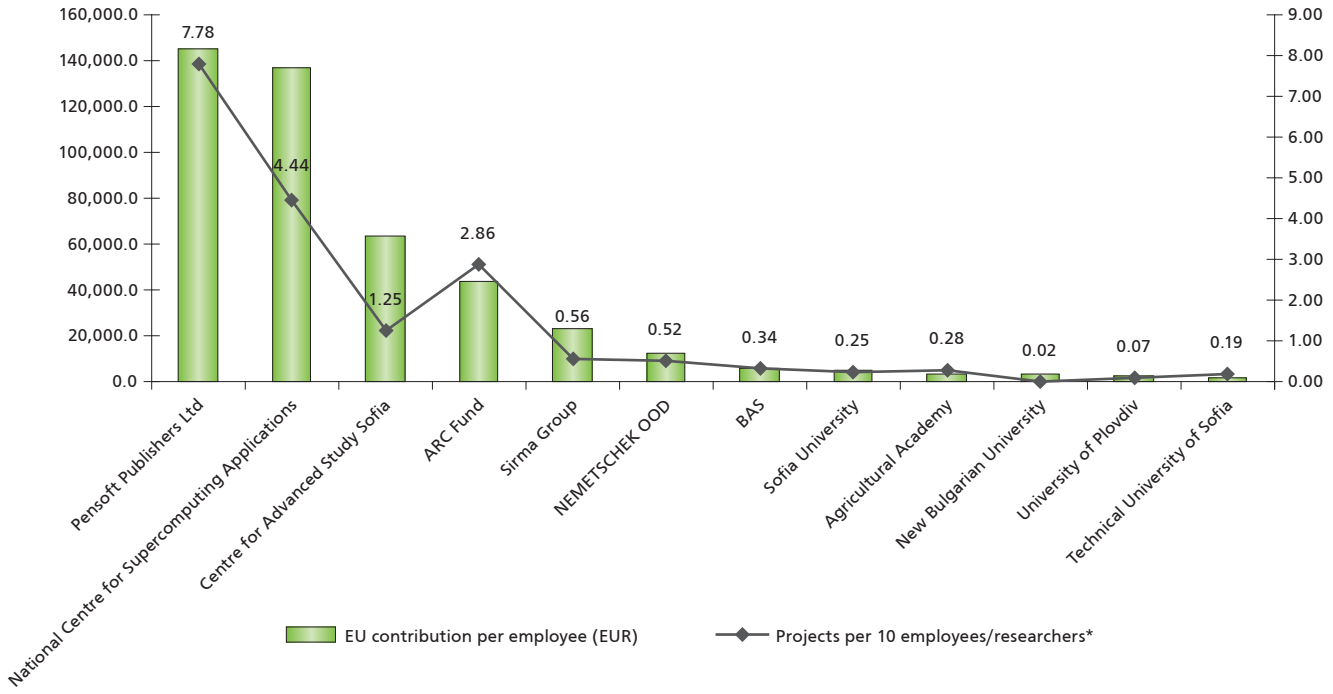
growth, and its strategic framework for research and technological development. When a government is aware of and acts on its responsibility for promoting R&D and innovations, this reflects positively on the choice of national priorities and their implementation. For example, while **for Bulgaria, Slovakia and Romania it is FP7 that effectively sets the choice of priorities, Estonia and the Czech Republic first choose critical fields for development – aligned with their national potential – and only then adapt them to FP7 objectives**.

Box 5. NGOs STRONGLY REPRESENTED IN EU FRAMEWORK PROGRAMMES

The 2012 METRIS Report for Bulgaria[30] has ranked ARC Fund among the **Top 5 Best Performers in FP7** from Bulgaria in terms of participation projects and EU financial contribution per employee.

In absolute values, ARC Fund ranks 7th, behind the Bulgarian Academy of Sciences (BAS), St. Kliment Ohridski Sofia University, Sirma Group, Paisii Hilendarski Plovdiv University, the Agricultural Academy and New Bulgarian University. ARC Fund ranks fourth in terms of EU funds per employee[31] and third in terms of number of projects per employee.

Figure 42. LEADING BULGARIAN RESEARCH PERFORMERS IN FP7 (2007 – 2012)



The growing role of NGOs is a new trend in FP7 that was not there in FP6. BAS, with its numerous institutes, and Sofia University remain in the lead, but business enterprises and non-for-profit organisations, ARC Fund among the latter, have entered the Top 10 for the first time. Business enterprises such as Sirma Group and NEMETSCHEK, both being ICT companies, and other not-for-profit organisations, such as the Centre for Advanced Study Sofia which supports individual academic research projects, have made large leaps into the Top 10.

Source: ARC Fund calculations, based on the FP7 data – MES, 2013.

[30] METRIS stands for „Monitoring European trends in Social Sciences and Humanities" – a platform, supported by the EU.

[31] Only full-time research and teaching staff (except for administrative and any other supporting personnel) are counted for the academies and the universities, while for the business enterprises and not-for-profit organisations the full-time staff regardless of the employees' functions (e.g. incl. administrative, technical, etc.) is taken into consideration.

Human Capital for Innovation

A picture of the personnel engaged in R&D, including academic and technological activity, reveals the level of human resources available for the creation, application and dissemination of new knowledge in the field of technologies. Employment in high-tech sectors reveals the country's specialisation in areas with a high level of innovation activity.

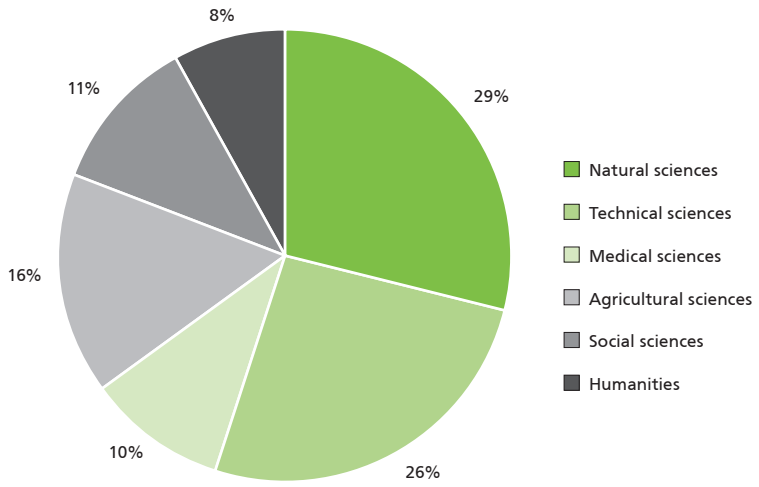
The sustainability of human capital has always been a condition for long-term economic growth. The true competitive advantage of a nation consists of its capacity to ensure "constant supply" of highly educated human resources. This process requires a long-term vision and careful planning as the training of workers, more specifically those that the economy needs, cannot be done easily and quickly. Famous Israeli entrepreneur Yossi Vardi[32] explains the dynamic development of ICT not only with the funds invested by the government, not only with a country's specialised high-tech military units, but above all the people. Competitiveness, constantly striving to be first, trying regardless of failures – all this is taught from the earliest age. It is the change of mentality that takes years.

One of the most important factors directly influencing human capital is education. That is why policy decisions should have a priority focus on education. However, while there is much talk about education as a priority, government efforts are not actually aimed at it. According to Eurostat, in 2010 Bulgaria and Romania were the countries in this region which set aside the least funds for education – respectively EUR 2,078.6 and EUR 2,639.7 per capita a year. The average level for EU is over EUR 6,000. The task of aspiring after European and global level of education with minimum funds is a formidable one.

The issues of *Innovation.bg* over the past five years have repeatedly underscored the need of investments in human capital, as well as the need of reforms. This year, these needs should be emphasised even stronger. The report of the National Audit Office,[33] published on 2 October 2013 and focused on the career development of higher education graduates, confirmed the recommendations of *Innovation.bg*. The report finds that there is no clear and comprehensive vision about the future of higher education, mostly because of the lack of a strategy for the development of higher education. The findings are that conditions for a better match between the demand and supply of labour in Bulgaria have not been created. In addition, there are no short-term or long-term forecasts about the needs of the economy for a workforce with certain qualifications, which makes governance decision-making in the field of the labour market and higher education risky. This exacerbates problems on the labour market and for the competitiveness of the economy.

In fact, the reform in higher education is one of the conditions the EC sets down for member countries so that they could receive European funds for investment during the 2014 – 2020 budget. The reason is that EU funds should be used only in sectors which are reformed, effective and will contribute in the long term to the achievement of the Europe 2020 objectives.[34] Not implementing reforms would lead to

Figure 43. R&D STAFF BY SCIENCE FIELD IN FULL-TIME EQUIVALENT, 2012



Source: NSI, 2013.

[32] Yossi Vardi, godfather of Israel's hi-tech industry, accessed on 10.10.2013 at http://www.bbc.co.uk/news/business-15888318

[33] Сметна палата, *Одитен доклад за извършен одит на реализацията на завършилите висше образование на пазара на труда за периода 01.01.2009 до 31.12.2012 г.*, accessed on 15.10.2013 at http://www.bulnao.government.bg/index.php?p=2729

[34] Table of Ex Ante Conditionalities in Annex IV to the draft regulation for determining generally applicable provisions for the funds included in the General Strategic Framework and responsible institutions, accessible at www.eufunds.bg

foregoing European funding and to additional slowing down of R&D in Bulgaria. In this sense, Operational Programme Science and Education has the unique chance to support research ideas that aim at growth and employment. Funds for innovation and science should not be channelled towards covering the current expenses of universities or research centres. Such requests have been made by universities because of pessimistic data about the annual budgets of public and private educational institutions. Academics believe that universities should be turned into powerful research centres. This means appropriate remuneration of researchers, moderate workload in teaching and good integration with their European partners within the European Research Area.

The private sector is also important for quality education; business and educational institutions should cooperate as much as possible. The main recommendations to higher education institutions include students having choice of subjects and courses that enhance their specialisation, as well as introduction of more flexible educational programmes that would allow them to combine study and work.

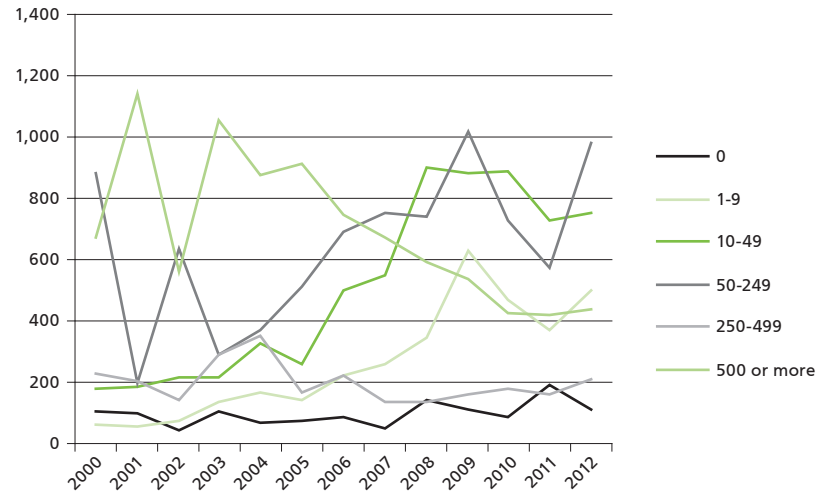
NSI reports that researchers accounted for an average 65 % of the staff engaged in R&D in 2000 – 2011. The total number of researchers increased by 28.84 %, the share of women researchers also rising. In 2000, male researchers were 19 % more than female researchers, while in 2011 the difference was 4 %.

Technical staff accounted for an average 23 % of those engaged in R&D in 2000 – 2011. The trend for the total number of technical staff was to decline over the period. Support staff was an average 12 % of those engaged in R&D in 2000 – 2011. It changed little over the period, fluctuating within 10 % – 14 %, the trend

Figure 44. R&D STAFF BY SCIENCE FIELD

Source: NSI, 2013.

Figure 45. R&D STAFF IN ENTERPRISES BY SIZE OF ENTERPRISES



Source: NSI, 2013.

from 2009 to 2011 being a 1 % decline each year to reach the lowest value of 10 % in 2011.

NSI data for 2013 show that there is a continuing prevalence of research staff in the natural sciences, followed by those engaged in technical and agricultural sciences. In addition, the data for 2012 show that even after the increase on 2011, there was still a 20 % decline of researchers engaged in R&D in technical sciences compared to 2009. This decline could be explained by the mobility of researchers in the EU and beyond. Thus, given that the future lies in technologies, government policy should provide incentives for young people to choose the technical sciences so that research in these fields could continue.

There has been a considerable increase of young people – the 'under 25' and '35-44 years' categories – in

the state sector in 2012 compared to 2005. In the higher education sector, an increase of staff engaged in R&D was registered in all age groups, the most significant being in the '35-44 years' category (over 2.5-fold in 2012 compared to 2005).

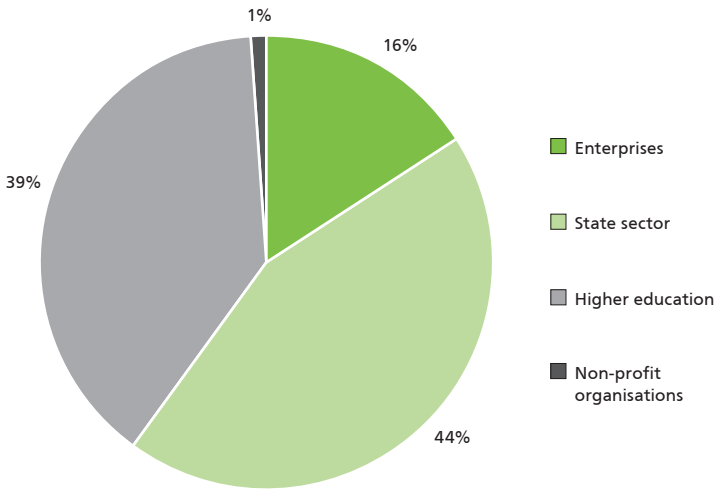
Small and medium-sized enterprises continued to be leaders in terms of employed researchers. This corresponds to the findings of European Commission reports that small and medium-sized enterprises are frequently more innovative, particularly in sectors such as ICT, because their size and flexibility allow them to take risks and to experiment. In other sectors, however, such as pharmaceuticals and the food and beverage industry, serious investments are necessary which small companies can barely afford.

The increased number of doctoral degree holders among R&D staff could be explained by the larger number of young researchers in higher education and their desire for career development. The trend is definitely on the rise after 2000.

According to the European Commission report *Towards Knowledge-driven Reindustrialisation*,[35] **there is a discrepancy between the needs of the labour market and the demand for qualified staff in Bulgaria.** These conclusions are also confirmed by the results of the National Audit Office report on the employment of higher education graduates which notes that for the period 2009 – 2012 the largest government determined student quota[36] was in the social, economic and legal sciences, which accounted for 35-36 % of the overall government quota. Little is done by the Ministry of Education and Science to promote cooperation between universities and business, thus not supporting the adequate training of students for actual employment and the transparent and effective management of higher education institutions. **Only a quarter of graduates work at positions requiring higher education. Nearly half of the graduates hold jobs that require a lower degree of education than theirs.** These facts should justify the **application of the dual system** characteristic of Germany, Austria and Switzerland, countries of low unemployment levels. The reason for that is that they provide vocational training in schools combined with apprenticeships in industry. Thus, students are ready to start work at the moment of graduation.

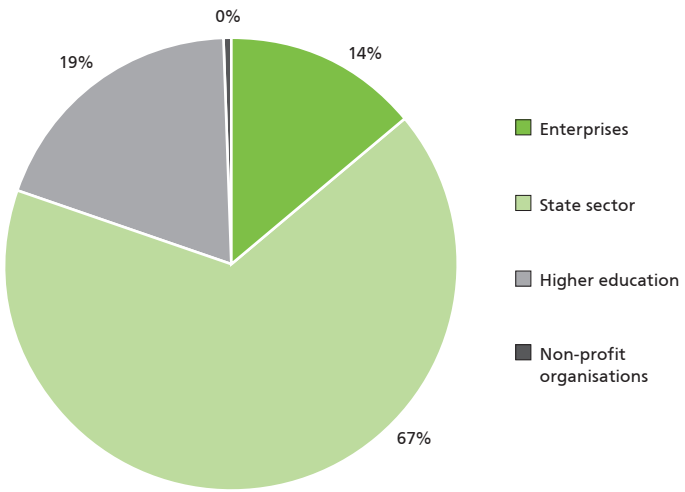
The need for personnel trained in the technical sciences is acknowledge by the Grand Coalition for Digital Jobs initiative of European Commission President Jose Manuel Barroso. He called on enterprises in the field of digital technology, governments and

Figure 46. R&D STAFF BY ECONOMIC SECTOR, 2011



Source: NSI, 2013.

Figure 47. R&D STAFF BY ECONOMIC SECTOR, 2000



Source: NSI, 2013.

[35] Competitiveness Report 2013, accessible at http://ec.europa.eu/enterprise/policies/industrial-competitiveness/competitiveness-analysis/european-competitiveness-report/files/eu-2013-eur-comp-rep_en.pdf, accessed on 14.10.2013.

[36] Determined annually by the Council of Ministers for state-subsidised universities.

training and education sectors to join the coalition. The objective is to address the expected shortfall of up to 900,000 ICT jobs expected in Europe by 2015. European Commission studies indicate that despite the current levels of unemployment, the number of digital jobs is growing by more than 100,000 per year. Yet the number of ICT graduates and skilled ICT workers is not keeping up.

Educational resources, teaching and learning change under the impact of ICT. The e-learning market, which holds 30 % of the entire education market, is expected to grow 15-fold in the next ten years. That is why the objective of the EC is to enable all Europeans to avail themselves of these changes.

Information and Communication Technologies

Information and communication technologies (ICT) as a factor of economic and social development is among the priorities of the next programming period of Europe 2020 and its two pillars Digital Agenda for Europe (DAE) and Innovation Union. According to the latest DAE assessments, an ICT ecosystem is a key growth factor in the EU having contributed 20 % to the rise in productivity, 5 % to the total GDP and 25 % of the business R&D expenditures by 2010.[37] DAE has seven pillars which set the framework for the development of all member states; in addition, the Agenda provides thirteen specific targets measured by a Scoreboard and achievable in each country within a period of time.

Table 16. BULGARIA'S PROGRESS ON THE SCOREBOARD OF DIGITAL AGENDA EUROPE

Pillars	Targets	Deadline	EU progress by end of 2012	Bulgaria progress by end of 2012
Pillar I: Digital Single Market	Fast (>30 mbps) broadband coverage for all	2020	54 %	61 %
	50 % of household taking up broadband subscriptions (>100 mbps)	2020	2 %	1 %
Pillar II: Interoperability & Standards	100 % increase (on 2009) in ICT R&D public spending	2020	60 %	..
	Roaming at national prices	2015	33 %	~30 %
Pillar III: Trust & Security	33 % of SMEs selling online	2015	13 %	4 %
Pillar IV: Fast and ultra-fast Internet access	20 % of population buying online cross-border	2015	11 %	4 %
	50 % of population buying online	2015	45 %	9 %
Pillar V: Research and innovation	60 % of disadvantaged people using internet regularly	2015	54 %	29 %
	75 % of population using internet regularly	2015	70 %	50 %
Pillar VI: Enhancing digital literacy, skills and inclusion	15 % of population having never used the internet	2015	22 %	42 %
	50 % of population using e-government	2015	44 %	27 %
Pillar VII: ICT-enabled benefits for EU society	25 % of population using e-government and returning forms	2015	22 %	11 %
	Broadband coverage for all	2013	95.5 %	90 %

Source: Digital Agenda Scoreboard progress reports.

[37] SEC(2010) 627. Europe's Digital Competitiveness Report, EC, 17.5.2010.

Eleven targets are related to the availability of broadband internet as a precondition for the functioning of an ICT ecosystem. Eight targets related to the ICT skills are relevant to the efficient use of the opportunities provided by an ICT ecosystem (e-commerce, e-learning, e-health, e-inclusion) based on broadband access. In addition, there is the role of business – primarily SMEs – in building a competitive and innovation-based economy and raising the efficiency of public services through public-private partnerships for e-government.

Advantages and challenges to broadband access in Bulgaria

Both the Innovation Strategy for Smart Specialisation and the National Development Programme: Bulgaria 2020 consider digital growth and innovation in business and society as mutually reinforcing factors of economic and social development. Bulgaria is among the leading countries in Europe and among the top 10 countries worldwide in terms of fast and ultra-fast internet coverage but is trailing the rest of the EU as regards penetration and use of internet services by the population. In addition to being widely available, broadband access is also relatively inexpensive, including in terms of PPP. Other advantages include the level of use of internet by enterprises and the presence of an internationally competitive ICT sector, including some Bulgarian companies being global leaders in their niches.

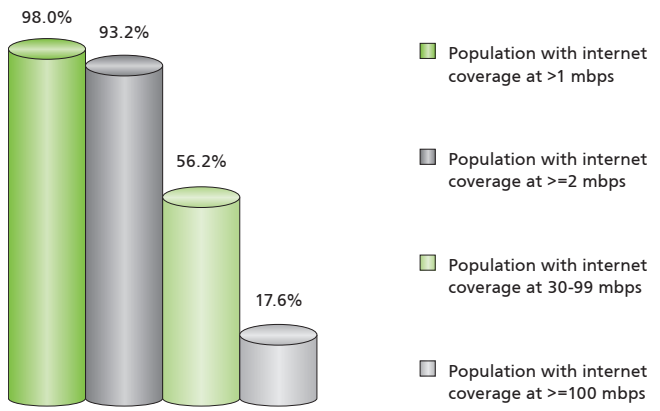
Making good use of this widely available broadband coverage is hampered mainly by the lack of long term national policies that are both effective and well-coordinated. In the last two decades, broadband coverage has grown mostly on the basis of business and technological models developed in an environment of poor regulation, including lack of protection of smaller businesses from the dominant position of the traditional telecom operator in issues such as the use of its national infrastructure and last mile access. The internet retail market is among the most compartmentalised in Europe – according to the Communications Regulation Commission, sectoral regulator, in 2012 there were 1,150 businesses licensed to provide end-user access, with about 800 being actually operational. Still, despite the large number of internet providers, the trend is towards market consolidation; currently the large national and regional operators are between 10 and 15 having 50-70 % of the market in terms of number of customers.

The 2012 Broadband Coverage Study (BCS), which ARC Fund regularly conducts in Bulgaria,[38] finds that intensifying competition has levelled the prices around the country, with customers in smaller towns preferring cheaper and more basic services, while in large cities customers prefer more sophisticated services at higher prices. Newly developed networks in rural areas allow high speeds, including ultra-fast (>100 mbps), access mostly by combining fiber and LAN technologies, provided there is sufficient demand by end-users.

A notable trend of the last two years is the growth of fiber networks within and between small towns which small local operators use to provide bundled services, often as intermediaries of large national providers. A key shortcoming of national policy in this field is failure to enforce the requirement for providers to supply information to the Central Cadastre about newly created networks which hampers the planning of public investment in broadband infrastructure, the mapping of current scope of access and technologies in use.

As regards end-users access speed, the ARC Fund BSC findings indicate that the official statistics used for DAE Scoreboard reporting underestimate the actual availability of basic (>1 mbps) and fast (>30 mbps) internet access. For a second year in a row, the Study finds that almost the whole population (98 %) resides in places where basic access is provided and over half (56 %) in places with fast internet. Bulgaria is thus among the leading EU countries in terms of broadband coverage but capitalising this advantage for digital growth would be jeopardised in the short term unless the advances made by

Figure 48. BROADBAND COVERAGE IN BULGARIA BY DECEMBER 2012



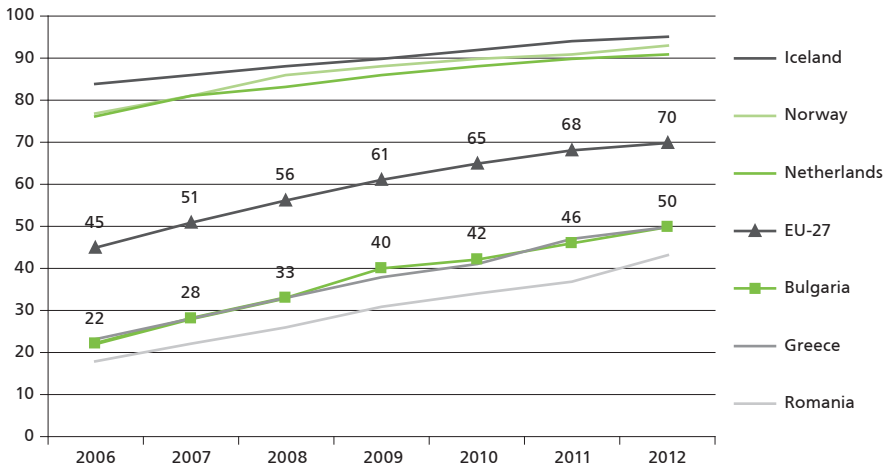
Source: ARC Fund BCS 2012.

[38] The ARC Fund Broadband Coverage Study has been conducted since 2010 as a representative national survey looking into the elements of internet access (packages, speed and price, types of technologies used) and social and economic factors (demographics, public services such as education, healthcare, social, household use of internet, etc.) at the settlement level.

business are not supported by a government policy of expanding public e-services, encouraging the upgrading the e-skills of the public, mostly among students, and enhancing e-inclusion, mostly of people with disabilities.

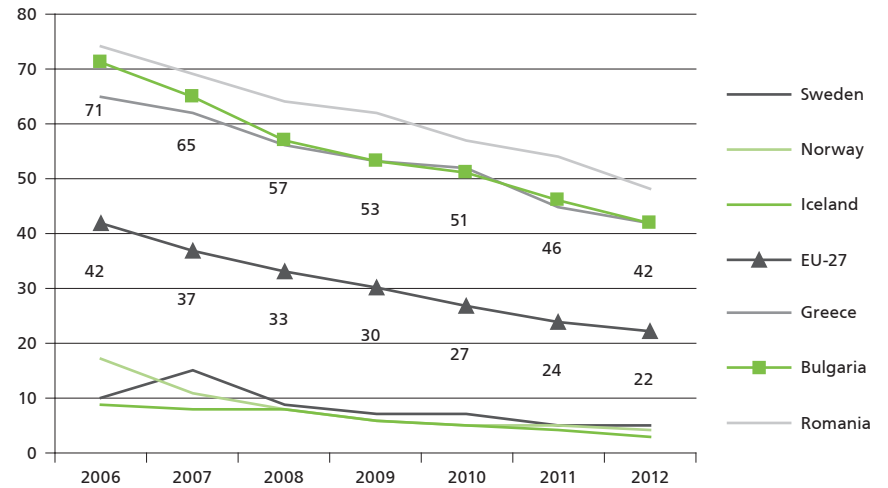
In the last years, many European countries have increased their public investment in broadband infrastructure mostly in rural areas. The largest projects have been implemented in the UK, Italy and Germany but similar initiatives are also taking place in other countries, including in Central and Eastern Europe. In 2012, the European Commission took 21 decisions regarding broadband projects involving public funding. The state aid allowed was approximately EUR 6.5 billion which is over three times higher than the amount approved in 2011, with almost the whole amount (6 bln) in the three countries mentioned.[39] In Bulgaria, the EUR 20 million procurement, financed by OP Regional Development, for a contractor to build broadband infrastructure in rural areas only started at the end of 2012 with a two year delay.[40] Thus, there was an overall change of model from an open network with access points in small towns to an open network complementing the main public infrastructure with access points in municipal centres. This is the largest project in this sector for the whole 2007 – 2013 programming period. However, lack of sustainability of policies and project management changes led to a change of model at the time when, in 2011, the country was on the verge of receiving the state aid approval and thus the procedure had to be restarted. Public procurement procedures are thus taking place before the EC decision on the state aid and risk the termination of contracts should the aid be disallowed.

Figure 49. REGULAR (ONCE A WEEK) INTERNET USE, % OF THE POPULATION



Source: Eurostat, 2013.

Figure 50. PERCENT OF POPULATION HAVING NEVER USED INTERNET



Source: Eurostat, 2013.

ICT skills and training

Together with Greece and Romania, Bulgaria is at the bottom of the EU in terms of the share of the population who use internet regularly (at least once a week). In 2012, only half (50 %) used internet at least once a week, which is a slight increase compared to the 46 % of the previous year. This is well below the EU average and half the level of the countries with most active internet users – Iceland and Norway. The increase in the use of internet in Bulgaria has been 127 % since 2006 which ranks Bulgaria second after Romania with 139 %.

Bulgaria was next-to-last in EU in 2012 as regards the share of the population having never used internet (42 %), which is twice the EU average (22 %), with a 4 point positive

[39] Digital Agenda for Europe Scoreboard 2013.

[40] The beneficiary of project BG161PO001/2.2-01/2011 "Support for the development of critical, protected, secure and reliable public ICT infrastructure" is the public body Executive Agency "Electronic Communication Networks and Information Systems."

change on the previous year. This corresponds to the shortage of computer skills compared to the EU average and to the leading countries.

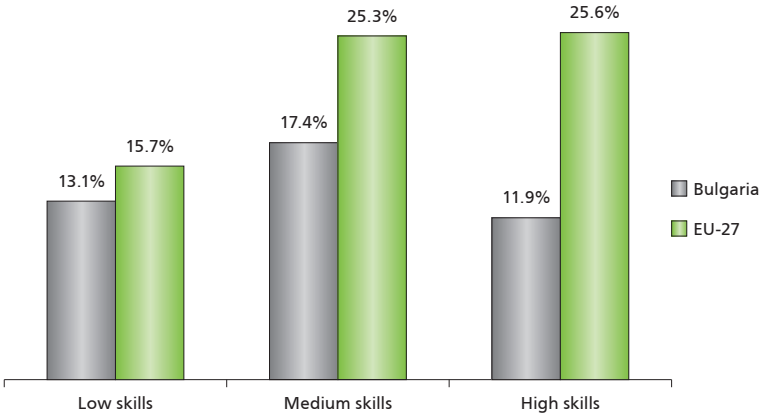
In 2012, almost half of the population (42.4 %) had at least basic computer skills, which is about a quarter less than the EU average of 66.6 %. More sophisticated skills are unevenly distributed among the population and point to two unfavourable trends. On the one hand, with more complex skills the gap between Bulgaria and the EU average grows, indicating that the country is dropping behind in terms of specialised skills which hold the key to higher competitiveness and products and services with higher added value. On the other, Bulgaria is also behind the EU average at all levels of computer skills.[41]

Bulgarian policy on e-skills is focused on the formal education system – from pre-school to higher education. Retraining and further education opportunities are provided both by the business sector and the formal education institutions, including through funding from OP Human Resources Development.[42]

Bulgaria has had some traditions in high-skilled IT specialists, including school and university graduates. In the last decade, however, the quality of ICT education has declined as witnessed by the managers of leading ICT companies who report that in the last five years the time needed for company training of a student with no work experience has doubled – from six months to one year.[43] Government policy in support of introducing IT in the formal education system has been focused on investment in technologies and services[44] and less on incentives and the curriculum.[45] While these investments boosted digital literacy, especially in primary and secondary schools, the main challenge remains the change of the curriculum for these specialised skills so they could be relevant to the modern labour market requirements. This is especially applicable to higher education, where university autonomy is used as an excuse for a constant increase in the range of bachelor and master's programmes on offer, often at the expense of the quality of education due, among other things, to shortages of faculty.

ICT enterprises are leaders in the business sector in encouraging and supporting science and education through various initiatives ranging from public presentations and lectures to competitions, internships, and even academies. Many of these initiatives have been carried out in cooperation with scientific and educational institutions thus leading to sustainable partnerships among education, business and science. However, there is no government policy in support of these initiatives, despite the frequent statements about the need to bring education and science closer to the needs of the labour market. Some of these institutionalised initiatives include the academies of multinationals such as CISCO u Microsoft[46] and of leading Bulgarian companies such as Musala Soft, Telerik, the training centres created by TechnoLogica, SAP Labs

Figure 51. LEVELS OF COMPUTER SKILLS 2012, % OF THE POPULATION



Source: DAE Scoreboard 2013, Country Presentation – Main Indicators.

[41] Digital Agenda for Europe 2020: Internet Activity and Digital Skills in Bulgaria – 2013 report, p. 2, EU, 2013. https://ec.europa.eu/digital-agenda/sites/digital-agenda/files/BU%20internet%20use.pdf

[42] According to MES (Managing Authority of OP Human Resources Development) approximately 10,000 individuals have taken retraining courses in the period 2007 – 2012. Half of these have taken a general or specialised ICT course.

[43] Estimated on the basis of in-depth interviews with managers of ICT companies, mostly in software development.

[44] For example, the national programmes "Modernisation of vocational education" and "ICT in schools". Despite investment in technologies and services, in 2012 the number of computers (internet connected and standalone) in Bulgarian schools is at half the EU average. (Digital Agenda for Europe 2020 report on Survey of Schools: ICT in Education. Country Profile: Bulgaria, November 2012).

[45] For example, the project "Improving the quality of education", funded through OP Human Resources, develops drafts of the state educational requirements for the compulsory and specialised learning of school subjects at the primary and secondary school level, including in ICT. A similar, although smaller project was the joint initiative between the MES and the British Council "Skills for employability" (2010 – 2012).

[46] For example, there are Cisco network and Microsoft IT academies with a number of universities (Technical University Sofia, Sofia University St.Kliment Ohridski, American University in Bulgaria, Technical University Gabrovo, Technical University Varna, New Bulgarian University, etc.), with industry associations or NGOs (Bulgarian Industrial Association, various community centres), with a number of secondary schools (the National Professional School for Precision Engineering and Optics, the Sofia High School of Mathematics, Sofia Professional School of Electronics, etc.) and with private and public enterprises (TechnoLogica, Information Services, etc.).

Box 6. TECHNOLOGICA INTERNSHIP PROGRAMME

TechnoLogica is a leading Bulgarian software company, which since 1990 has been developing a comprehensive range of information technology services including implementation of information systems, software development, consulting and specialised training.

TechnoLogica's internship programme was started in 1993 and provides an opportunity for students from Sofia University St. Kliment Ohridski, the Sofia Technical University and the University for National and World Economy to be employed over the summer period as paid interns at the company. Interns receive certificates and some stay on as full time employees.

In 2012, sixteen students, chosen through a selection process that included an interview and, for some positions, an exam joined the company team for three months. At the beginning, interns are trained in the high-tech and information systems used at TechnoLogica, and then join specific project teams. Each intern is assigned an experienced mentor who provides guidance and supervision of the intern's work.

In 2012, in addition to the internship opportunities in IT, the programme provided training in consultancy on ERP, HR and BPM systems.

The challenge is not only to provide paid internship which shows students that integrity and innovation could be combined in a business in Bulgaria, that there are good career opportunities and allows them to study the work process in a company ... The challenge is to train and motivate mentors and to use tasks from actual projects that would be both interesting and correspond to the skills of interns, says Mr. Ognian Trajanov, CEO of TechnoLogica.

Source: TechnoLogica, 2013.

Bulgaria, etc. These initiatives alone train between 10 and 20 thousand individuals annually,[47] mostly students and university graduates. In comparison, the National Evaluation and Accreditation Agency (NEAA) determined enrolment cap for the three ICT-related vocational subjects taught at universities for the 2012/2013 academic year was 34,960 students.

The further education initiatives of the ICT business go beyond training courses and are complemented by various initiatives aimed at enhancing a wide range of skills and job prospects such as programming competitions, support for participation in international competitions, learning of entrepreneurial skills, various internship programmes conducted as a partnership between an educational institution and a company, opportunities for research at the development divisions of companies or in joint publicly funded projects.

The role of the ICT sector for a competitive and innovation-driven economy

According to the NSI, there are a little over 9,000 businesses in the ICT sector, most of which (89 %) during the last three years being micro enterprises, while medium and large ones account for just 2.5 %. There has been a 26.4 % increase in the number of enterprises in the sector between 2008 and 2011; most of this growth is due to micro businesses, while medium-sized have shrunk and large ones mostly unchanged in numbers.

In the last decade, Bulgaria has become a preferred destination for outsourcing business operations from across the world, including in the ICT sector. This trend has slowed down in the last three years, mostly as a result of a quicker recovery in Asia, but the country is nevertheless maintaining a leading position. In one 2013 ranking, Bulgaria was fifth among 38 countries, down from fourth in 2010 but still being the most preferred outsourcing destination in Europe.[48] The latest 2011 A.T. Kearney index puts the country in the 17th place worldwide, down from 13th in 2010 but still leading Central and Eastern Europe ahead of Poland (24th), Romania (26th), Hungary (31st) and Czech Republic (35th).[49] The Gartner ranking of outsourcing destinations puts Bulgaria among the leading 30 countries in 2010 – 2011, number one in the EMEA (Europe, Middle East and Africa) region, again ahead of the

[47] In 2012, the Telerik software academy alone trained 7,050 individuals in 26 free courses in 13 subjects. In the 2012 – 2013 academic year, there were 2,050 full-time students, including a record 1,000 students in the Software Academy, 600 in the Children's Academy, 300 in the School Software Academy, 150 in the Algo Academy. Another 5,000 persons take part in online training. (National Newsletter No.4 for 2012, MES).

[48] Global Sourcing & Outsourcing Locations, http://www.sourcingline.com/outsourcing-countries

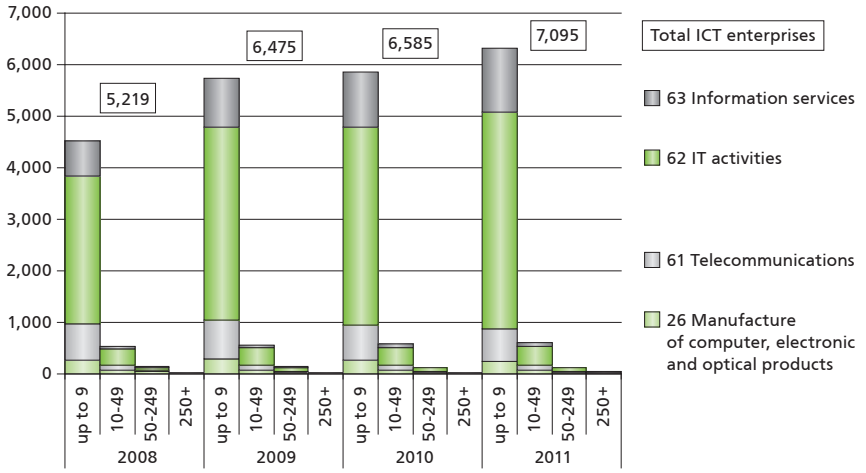
[49] Offshoring Opportunities amid Economic Turbulence. A.T. Kearney Global Services Location Index, 2011.

Czech Republic, Hungary, Poland and Romania.[50]

The slight loss of ground in these rankings since 2010 is reflected in the reduction of foreign direct investment in the ICT sector by 36.4 % in 2011 compared to 2008. The decline is most significant in telecommunications, while investment in the sector "IT activities" has grown by 64 % over the same period. The latter sector is the one with most R&D intensive innovative companies designing custom-made software and creating integrated IT systems.

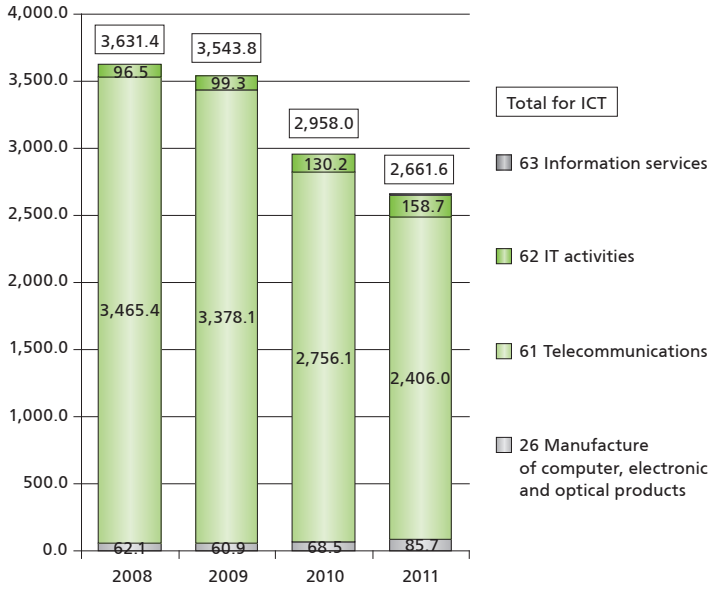
This is mostly due to Bulgaria and the ICT sector becoming, in the last decade, a successful model not only in outsourced call centres, software development and hardware production at low cost but also in providing an environment favourable to R&D and innovation which meets the needs of multinational companies. Several highly innovative ICT companies have had the greatest role in achieving this position. These companies, created by Bulgarian entrepreneurs in the beginning of the 1990s following the collapse of the national computer industry and system of research institutes, managed to become leaders in niche markets or create entirely new niches. This happened first regionally, then in Europe and even in the United States. The majority work for foreign clients which made the opportunities Bulgaria had to offer widely known, despite almost no support from government institutions. In many cases, investment and the entry of global companies in the Bulgarian ICT sector was done through the acquisition of Bulgarian companies with which partnerships had been established. The presence in Bulgaria of R&D units of large ICT companies (SAP Labs, Siemens, Johnson Controls, VMWare, Nemetschek, Sitel, Codix, Epic Electronics, etc.), as well as of

Figure 52. NUMBER OF ENTERPRISES IN SEGMENTS OF THE ICT SECTOR, BY SIZE



Source: NSI 2013.

Figure 53. FDI IN SEGMENTS OF THE ICT SECTOR, EUR MLN



Source: NSI 2013.

Bulgarian companies developing products and services for large multinational companies or in partnership with them (Sirma Solutions, Fadata, InterConsult Bulgaria, TechnoLogica, Datecs, Telerik, Musala Soft, Bianor, Haemimont, Telelink, Chaos Group, Rila Solutions, AMK Drive and Control Technology, Optix, Samel-90, Daisy Technology, etc.) makes the country more visible internationally and its reputation as outsourcing destination for services and high-tech innovative solutions.

The R&D focus of the ICT sector is evident also in the statistics on the R&D expenditure of the enterprises in the sector which have remained unchanged over the last four years,

[50] Gartner Identifies Top 30 Countries for Offshore Services in 2010 – 2011 (https://www.gartner.com/newsroom/id/1500514)

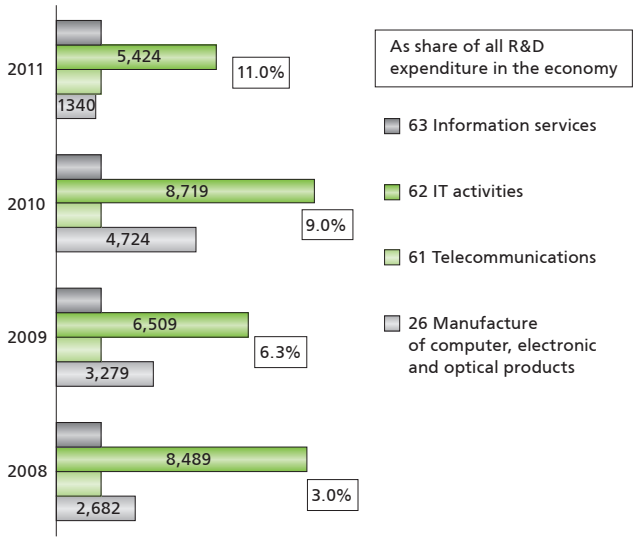
while the same expenditure is declining in the other sectors. This is all the more significant given that R&D spending by the ICT sector is underestimated in the official statistics because it is underreported by business as a result of the lack of government policy encouraging R&D and innovation in the sector.[51]

The added value generated by the ICT sector has risen by 10.1 % in 2011 compared to 2008 with the biggest contribution (39.8 % rise) made by the "IT activities" segment. Considered against the number of employed persons, the added value in the ICT sector is above the average for the economy, with "Telecommunications" being second only to "Mining of metal ores" for 2008 – 2011.

The rise of added value – in absolute terms and per employed person – is yet another sign that the ICT sector has established itself as competitive and innovation-driven. This is also evident in the emergence of Bulgarian ICT companies entering existing or creating entirely new market niches in which they become leaders both at home and worldwide. The trends identified in the previous *Innovation.bg* report are still valid:[52]

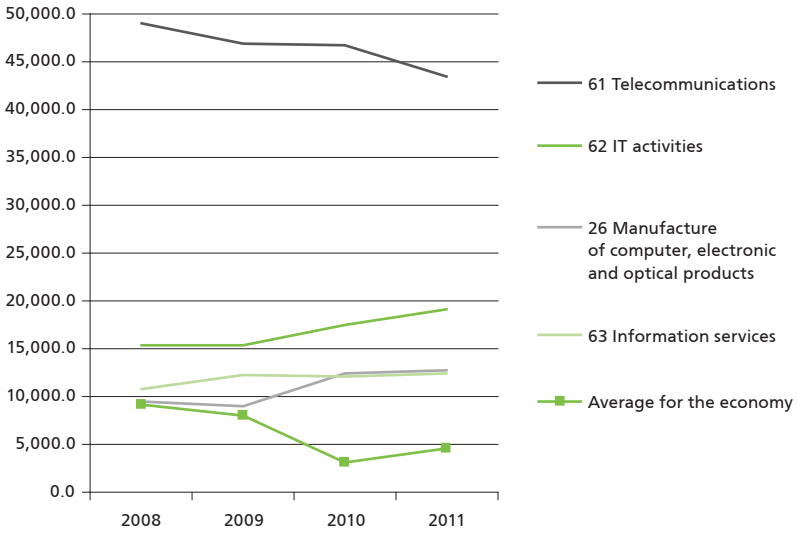
1. The main exporters in 2012 and 2013 were still the manufacturers of precision instruments, optical products and telecom equipment and, in the software segment, the designers of custom-made software. There are two types of companies in this group – local branches of multinational ICT companies, especially the ones which are R&D centres or are R&D intensive, and local Bulgarian ICT firms oriented towards foreign markets. Both types usually employ their own R&D units or staff working full time on the development of innovative products and services. Some Bulgarian companies have managed to establish themselves as long term partners or suppliers of multinationals in the ICT sector and beyond, such as Nokia, Lufthansa, Kongsberg Maritime, Unilever and others.
2. Telecom companies continue to grow innovatively in their capacity to create value added services. This segment of the Bulgarian market has been very dynamic in the last two years, mostly as a result of market consolidation and technological

Figure 54. R&D EXPENDITURE BY ICT BUSINESSES, BGN THOUSANDS



Source: NSI 2013.

Figure 55. ADDED VALUE PER PERSON EMPLOYED IN NON-FINANCIAL ENTERPRISES, EUR



Source: ARC Fund calculations based on NSI data, 2013.

[51] Business often reports its R&D to the national statistics as "usual activities" due mostly to the failures of policy, discussed earlier, as well as to the legal provision considering R&D costs "future expenditure" which increases the current tax burden against an expectation for future relief which – given inflation and economic uncertainty – is far from guaranteed.

[52] *Innovation.bg 2012: ICT and Innovation Demand*, p. 67.

convergence.[53] In many cases, local companies develop and launch their services in the country and then seek international outreach.

3. There are growing numbers of small highly innovative companies designing mobile applications, although this is not immediately evident in the official statistics. These are mostly micro-enterprises with 2-3 employees supplying directly end-users by developing mobile applications to be sold through the online shops of Apple and Google or working as sub-contractors to foreign companies.

Recommendations to ICT policy

1. E-government needs to be made a priority in all operational programmes for the 2014 – 2020 period. An integrated national strategy and institutional framework need to be created.
2. The advantages that Bulgaria has in the broadband coverage need to be utilised better. This could be achieved through an integrated approach to the provision of value added services by the public administration and business as a factor that could boost levels of internet use, which are still behind all other EU countries.
   a. The regulations requiring internet providers to report existing networks and those under construction to the Cadastre Agency need to be strictly enforced, which would allow better planning of government policies and investment;
   b. Appropriate standards need to be introduced for public access to information about available infrastructure and services provided by enterprises required to register with the Communications Regulation Commission, while at the same time the confidentiality of information that would violate the Personal Data Protection Act or is commercial secret is maintained.
3. Monopolies and oligopolies need to be better regulated in order to enhance the fairness of competition and remove entry barriers to markets, including through policies that facilitate foreign investment in the sector.
4. Encourage reporting of R&D in the sector (and the economy as a whole)[54] to the NSI by creating incentives for companies to report R&D and inform business of the applicable accounting and international standards in this field.
5. Increase the government quota and enrolment in ICT subjects in secondary and higher education.
6. Create incentives for business to participate in the planning and development of training programmes for the system of formal education, including promotion of ICT professions and entrepreneurship at all stages of education.

[53] Sometimes, these two processes undermine a competitive market and lead to monopolies and oligopolies, formed most often as a result of a merging of political with economic leverage. The current *de facto* monopoly on the broadcast of aerial digital TV is an example of this threat.

[54] This recommendation was detailed in *Innovation.bg* 2012, including an awareness campaign about the need to report R&D, directly approaching the companies involved in R&D but not reporting, development of special accounting modules for R&D and training for accountants, creating tax incentives, encouraging R&D reporting through incentives in the operational programmes, etc.

Innovations in Support of Sectoral Competitiveness

Innovation aimed at applying newly created or acquired knowledge takes place within the practice of individual companies which in turn are differentiated by sectors. In order for national and sectoral policies to achieve an impact on the speed and effect of innovation (intelligent and well thought-out regulation, educational and science-and-technology priorities, fiscal framework, public-private partnership rules) it is vital to understand the mechanism by which innovations are created.

That is why the assessment of the innovation potential of the Bulgarian economy, which is the focus of the present *Innovations.bg* report, should move down one level – to its sector-specific characteristics. **Sectoral differentiation reveals the way in which the participants in the technological chains and sectoral innovation systems interact in the process of creation, integration, and implementation of technological, organisational, and marketing innovations.**

The analysis of the sectoral innovation systems demonstrates the essence and importance of the innovation activity of the respective companies and thus facilitates the elaboration of **sector-specific pro-innovation policies and measures with a real impact on the economy**. The development of mechanisms of influence – not ones that are imposed from the outside but logically ensuing and suggested by the natural transformation processes within the respective sectors – ensures a healthier environment for the operation of the innovation ecosystem as a whole.

The report *Innovations.bg 2013* analyses the innovation potential of the **pharmaceutical sector** by examining the sector-specific technological chain, existing links and forms of interaction within the sectoral innovation system, and the factors that influence them.

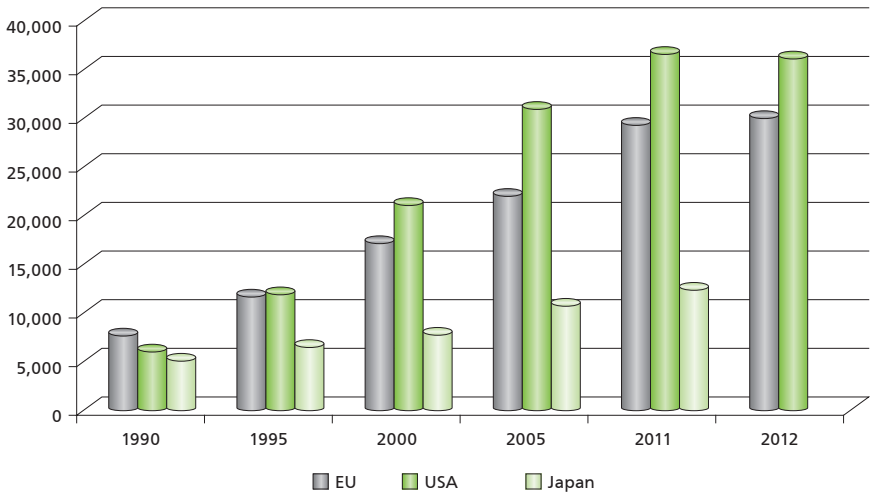
Pharmaceutical Sector

The European pharmaceutical industry contributes significantly to the economic welfare of Europe and the world by creating medicines, economic growth, and sustainable jobs. Pharmaceutics is among the few sectors in EU with a positive balance of trade in the past few years. R&D pharmaceutical companies in EU provide 700,000 jobs, and generic ones another 150,000. **Thanks to the highly qualified workforce and the existing legal framework for the protection of intellectual property rights, in 2012 the pharmaceutical industry in Europe invested EUR 20 billion in R&D.**

In 2012, the global pharmaceutical market (based on manufacturer prices) amounted to roughly EUR 667,653 million. North America (USA and Canada) constitute the largest pharmaceutical market with a share of 41 %, followed by Europe and Japan.[55]

The bulk of medications (88 %) are distributed among barely 18 % of the world population. Even more notably, 82 % of the population uses but 12 % of all medications produced. The markets of Brazil, Russia, India, China (BRIC), and South America are worthy of special attention. They are widely defined as 'generic' and 'developing' but now analysts have begun to refer to them as 'pharmerging'. The term did not get into use until 2006, when serious changes in the development of pharmaceutical markets were first observed. In 2009, the seven countries of BRIC, Mexico, South Korea, and Turkey displayed unprecedented pharmaceutical market growth which made up 51 % of the growth worldwide. At the same time, traditional markets such as North America, Western Europe, and Japan only accounted for 16 %. This was in sharp contrast to 2001, when the so-called pharmerging markets only accounted for 7 % of global growth versus 71 % for the traditional markets.[56]

Figure 56. R&D EXPENDITURES IN THE PHARMACEUTICAL INDUSTRY (1990 – 2012, MLN, LOCAL CURRENCY)



Source: EFPIA member associations, PhRMA, JPMA.

Economic profile and importance of the sector to Bulgaria's economy

The pharmaceutical industry is considered a priority sector in Bulgaria with potential for smart specialisation on the regional and national level.[57]

Some of the financial instruments encouraging innovation activity of businesses in Bulgaria included in the Operational Programme Innovation and Competitiveness 2014 – 2020 have been developed after analysis and assessment of leading traditional and high-tech industries in the country, including pharmaceutics.[58]

The pharmaceutical sector ranks among the top five processing sectors by a number of key indicators. While the manufacture of coke and refined petroleum products (NACE Rev. 2 Division 19) and tobacco products (D12) come first by turnover, number of employed persons and investment in durable assets, the pharmaceutical sector is in the lead by profit and labour productivity. The analysis of the statistical data shows the following ranking of the sector within manufacturing:

- **First place by average profit margin per enterprise – 19.7 %.** By comparison, other competitive sectors with high profit rates

[55] The Pharmaceutical Industry in Figures – Key Data, 2008 update – European Federation of Pharmaceutical Industries and Associations (EFPIA); The Pharmaceutical Industry in Figures – Key Data, 2012 update – European Federation of Pharmaceutical Industries and Associations (EFPIA).

[56] Tempest, B., "A structural change in the global pharmaceutical marketplace", Journal of Generic Medicines, 2010, 7.

[57] Draft Innovation Strategy for Smart Growth until 2020, 28 May 2013.

[58] Draft Operational Programme Innovation and Entrepreneurship 2014 – 2020, 11 July 2013.

are the manufacture of non-metallic mineral products other than rubber and plastic (19.3 %) and the manufacture of computer, electronic and optical products (18.1 %);

- **First place by export growth rate in 2011 from 2008** (117 %). With exports amounting to EUR 566 mln in 2011, the pharmaceutical sector ranks 9th in manufacturing;
- **Third place by investment in durable assets after the capital intensive and low-technology sectors** – BGN 2,053 thousand per enterprise or 123,180 thousand for the sector as a whole. Under this indicator, pharmaceutics is the only high-tech sector among the top five, with four times as large investments as in the next representative of high technologies – the manufacture of motor vehicles, trailers, and semi-trailers;
- **Third place by average labour productivity at the enterprise level**.

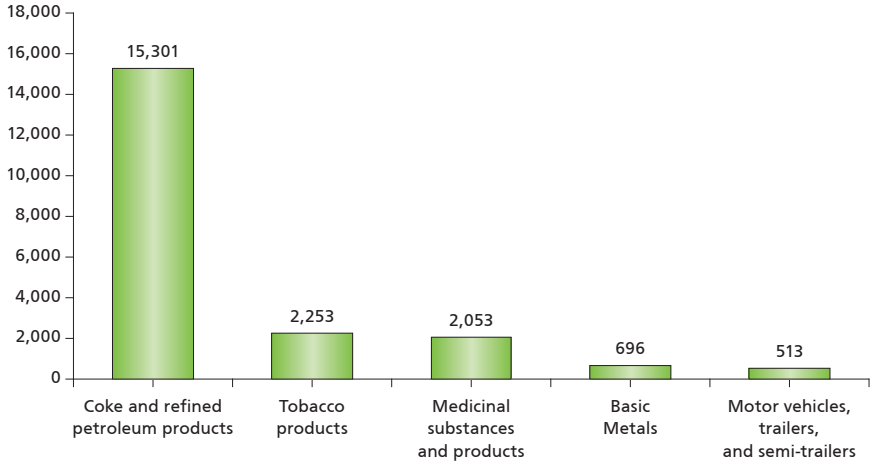
As of the end of 2011, there were a **total of 60 companies** operating in the pharmaceutical sector, of which 52 small and medium-sized enterprises with average workforce of 36, and 8 large companies with 720 employees on average. With average annual turnover per company of BGN 12.6 mln, in 2011 the **total turnover** of the sector amounted to BGN 756 mln.

Whereas in 2009 the **number of employed** in the sector amounted to 7,257 persons, as of the end of 2011, their number had increased by 5.2 % to 7,637. By this indicator, the pharmaceutical sector ranks second to last among the high-technology and medium-high technology industries in Bulgaria. The pharmaceutical industry's **share in value added** within manufacturing is 2.8 %. In absolute figures it amounts to BGN 252 mln, with the large companies in the sector accounting for 78 %, or BGN 197 mln. By comparison, 8,718 persons are engaged in manufacturing of computer, electronic and optical products and account for 2.4 % of value added in manufacturing.

Labour costs in the pharmaceutical sector constitute 41 % of the **value added**. Under this indicator, within the group of high- and medium-high technology industries, the manufacture of chemical products is the only industry registering a lower value of 39 %.

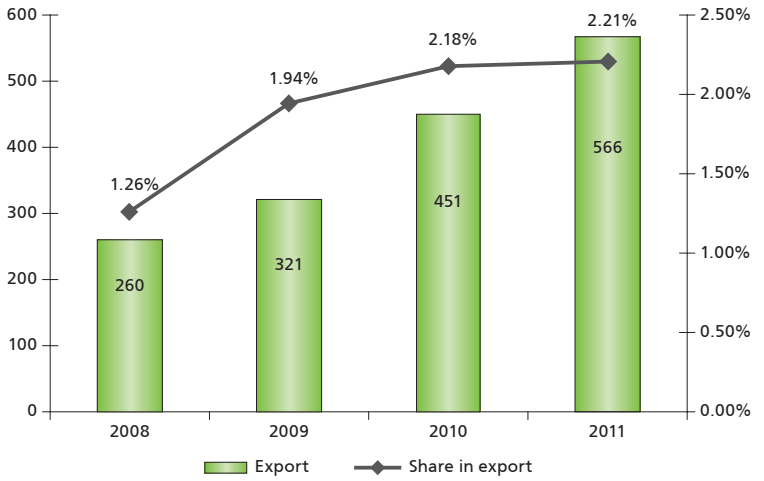
In the first three quarters of 2013, a **total of 283 – both new and rebranded – products have been introduced into the Bulgarian pharmaceutical market**. Of those, 46 are original brands and the remaining 237 are generic – a proportion that is rather common in other national markets within the EU, as well, reflecting the prevalence of generics.

Figure 57. INVESTMENTS IN DURABLE ASSETS PER ENTERPRISE, 2011, BGN THOUSANDS



Source: NSI, MEE, 2013.

Figure 58. EXPORT OF PHARMACEUTICAL SECTOR, MLN EUR AND % OF TOTAL EXPORT



Source: NSI, MEE, 2013.

The rate of penetration of innovative products has been highest in product classes where, in the past few years, there has been the most marked therapeutic progress on a global scale. However, the pace in Bulgaria is significantly slower that in the well-financed markets of EU (and Western Europe in particular) and has been directly dependent on the available financial resources at the National Health Insurance Fund (NHIF). **The time it takes for originator products to reach patients in Bulgaria is significantly longer and some innovations are never made available in Bulgaria at all.** Generally, **the countries of Eastern Europe are the last by rate of penetration of innovative products**.

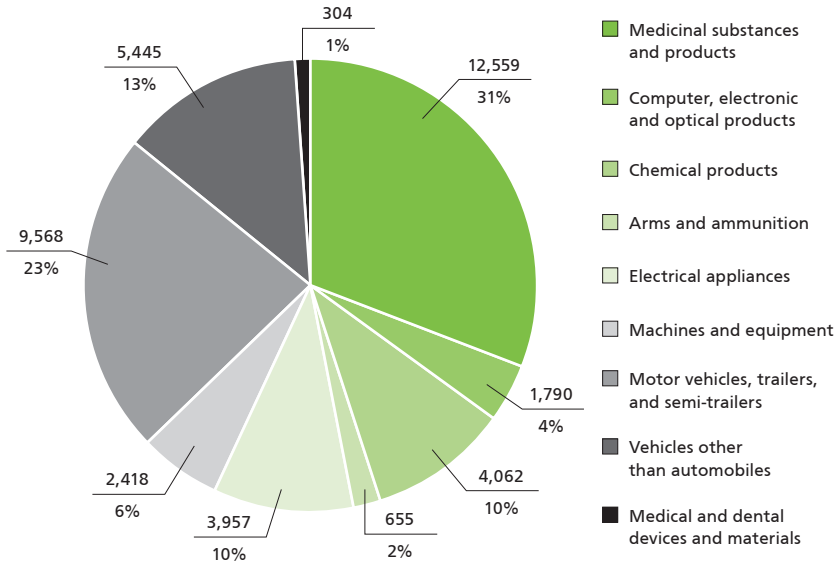
The data indicate that **pharmaceutical manufacturers in Bulgaria are generic and target the low-end price segment**. In the first three quarters of 2013, the domestic industry has brought to the market innovations constituting 0.16 % of the total market, versus 0.82 %, or five times as much, offered by the international companies. The difference is even more conspicuous in terms of value – 0.17 % versus 1.57 %, or 9 times. Clearly, the **domestic industry is offering cheap innovations without high-tech specialisation**. The domestic pharmaceutical industry is generic by inheritance from the former socialist bloc.

Innovation in the pharmaceutical industry

Unlike all other economic sectors which are largely conditioned by the market and the innovation of which is driven by a combination of technological advancement and consumer preferences, the pharmaceutical companies operate under the influence of a number of factors of a different nature:

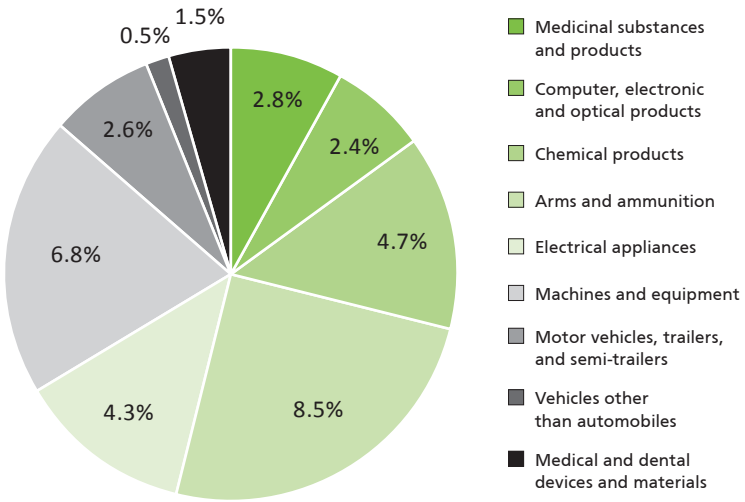
- **Pharmaceutical companies manufacture a special type of product**

Figure 59. ENTERPRISE TURNOVER IN HIGH AND MEDIUM-HIGH TECHNOLOGY SECTORS, 2011, BGN THOUSANDS



Source: NSI, MEE, 2013.

Figure 60. VALUE ADDED OF HIGH AND MEDIUM-HIGH TECHNOLOGY SECTORS, 2011, % OF MANUFACTURING



Source: NSI, MEE, 2013.

Table 17. NEW PRODUCTS INTRODUCED INTO THE BULGARIAN PHARMACEUTICAL MARKET IN THE FIRST THREE QUARTERS OF 2013

	Number	Market share in number of units sold	Market share in value terms
Generic	237	0.84 %	0.91 %
Originator	46	0.14 %	0.83 %
Total new products	283	0.98 %	1.74 %

Source: IMS Health Bulgaria, 2013.

A medicinal product is defined as any substance or combination of substances presented as having properties for treating or preventing disease in human beings or any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis.[59]

Pharmaceuticals are not ordinary goods. They are licensed for sale on the basis of whether they safely and efficaciously address a health care need, not because patients might have preferences concerning their shape, colour, taste or brand.[60]

- **The demand for pharmaceuticals is not determined by end consumers**

Regarding the demand for prescription drugs, the end consumer (patient) is not the one who makes the decision. It is typically made by the doctors who prescribe the medications; in some cases pharmacists in drugstores counter play a role (with the exception of over-the-counter drugs).

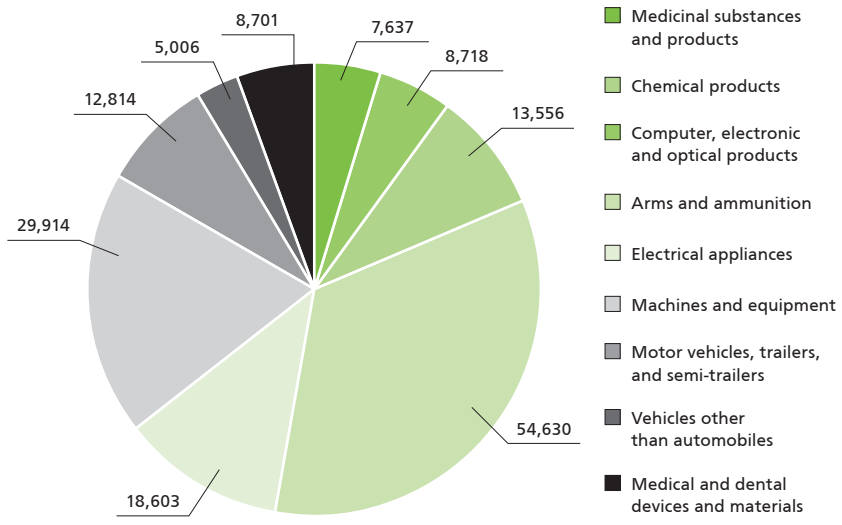
- **The cost of innovative pharmaceuticals is not a factor in purchase decisions and is typically shared between public funds and the end consumer**

In the use of medications, neither the patient, nor the prescriber or supplier covers the bulk of the cost. In EU member countries it is largely or fully reimbursed by the national health insurance funds. Prices are typically

[59] Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use.

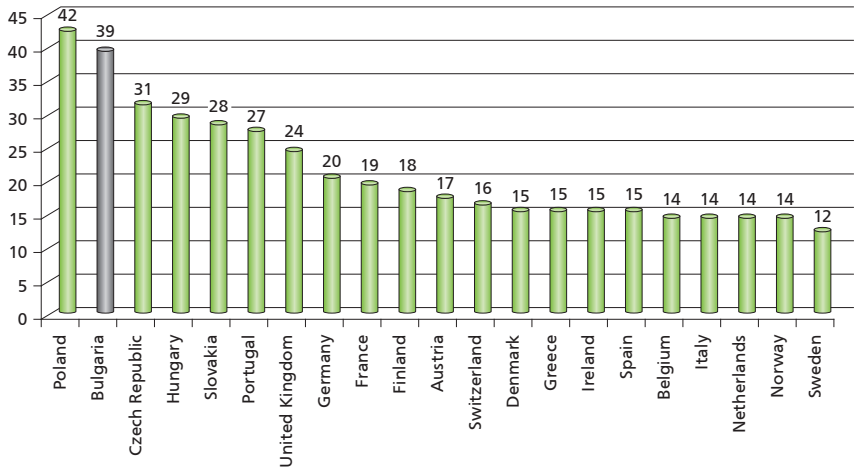
[60] Morgan S., Lopert R., Greyson D. "Toward a definition of pharmaceutical innovation", Open Medicine, Vol 2, No 1, 2008.

Figure 61. NUMBER OF EMPLOYED IN HIGH AND MEDIUM-HIGH TECHNOLOGY INDUSTRIES



Source: NSI, MEE, 2013.

Figure 62. GENERICS MARKET, 2011, % OF PHARMACEUTICAL MARKET IN VALUE



Source: IMS MIDAS, ex-mnf price, EUR, Total Rx market, drugs, 2011.

Table 18. ORIGIN OF NEW PRODUCTS INTRODUCED INTO THE BULGARIAN MARKET IN FIRST THREE QUARTERS OF 2013

Origin of innovation	Number	Market share in units sold	Market share in value
International	229	0.82 %	1.57 %
Bulgarian	54	0.16 %	0.17 %
Total new products	283	0.98 %	1.74 %

Source: IMS Health Bulgaria, 2013.

set as a result of a regulated decision-making process, sometimes involving negotiations among the stakeholders. When this is not the case, e.g. in countries with the so-called free price system, prices depend on regulated decisions concerning reimbursement of medication costs. As a result, doctors, pharmacists, and patients are not generally very price-sensitive regarding prescription drugs. The existing regulatory mechanisms reflect the wish of public and private health insurance funds to control healthcare budgets.[61]

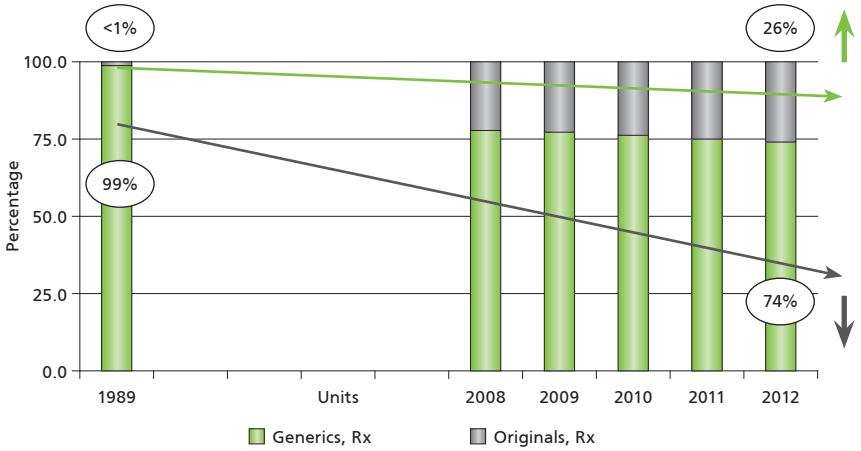
Even if the decision about the particular medication to be used in the treatment does not depend on the patients, in recent years increasing attention has been devoted to their involvement and adherence to the prescribed therapy. For that reason, pharmaceutical companies make efforts to provide a variety of medications and dosage forms that doctors can apply to the specific condition and needs of patients. The role of the patients is most important regarding treatment adherence and control over the therapy with a view to preventing complications.

The definition and even the very existence of '**pharmaceutical innovation**' vary depending on the viewpoint of the different stakeholders along the value added chain in healthcare. In terms of public interest and the medical science, what matters most is product – rather than process or marketing – innovation. And even though all too often the manufacture of new drugs based on new substances requires significant changes in the technological process, some authors only consider the creation of genuinely novel medicines as pharmaceutical innovation.

In keeping with the definition of the societal role of pharmaceuticals in terms of health outcomes and benefits, it should be noted that the creation of a new product cannot in itself be regarded as pharmaceutical innovation. The creation of a new molecule or new mechanism of action do not in themselves constitute proof of improved therapeutic possibilities and new drugs therefore need to be tested for effectiveness and safety. Furthermore, the criterion of effectiveness alone is not sufficient to qualify a given product as innovative. Pharmaceutical innovations create value to society by making it possible to generate improvements in patient health that were previously unattainable. **It is the uniqueness of such health improvements that defines pharmaceutical innovations**. A drug can be considered a pharmaceutical innovation only if it meets otherwise unmet or inadequately met health care needs.[62]

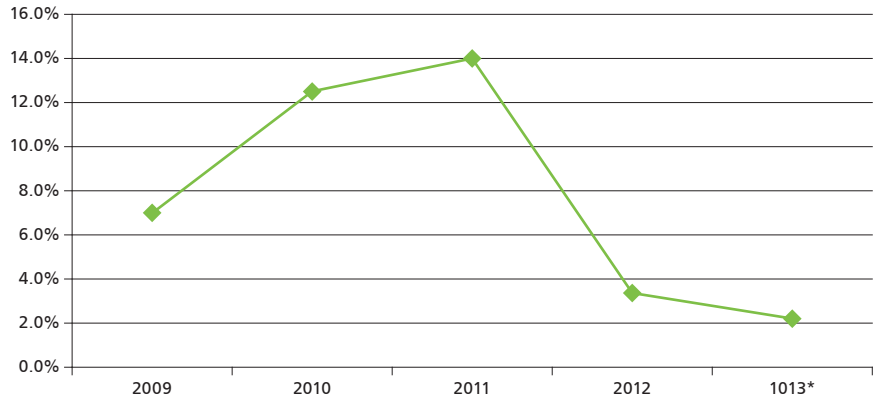
The differentiation between the various originator products in terms of

Figure 63. ENTRY OF NEW PRODUCTS INTO THE BULGARIAN PHARMACEUTICAL MARKET, %



Source: IMS Health Bulgaria, 2013.

Figure 64. GROWTH OF THE RETAIL PHARMACY MARKET IN BULGARIA, % ON ANNUAL BASIS



* The data on 2013 covers the first three quarters of the year.

Source: IMS Health Bulgaria, 2013.

[61] European Commission, Pharmaceutical Sector Inquiry Report, 2009., http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/index.html

[62] Morgan S., Lopert R., Greyson D., "Toward a definition of pharmaceutical innovation", Open Medicine, Vol 2, No 1, 2008.

innovation is typically determined by their therapeutic effects on the patients' health. In this sense, the pharmaceutical innovations fall into continuous, incremental, and radical depending on their importance for the treatment of hitherto incurable conditions and on the extent to which they improve the respective condition. **At present there are no harmonised European standards to determine the added therapeutic value provided by a new drug compared to existing therapies**.

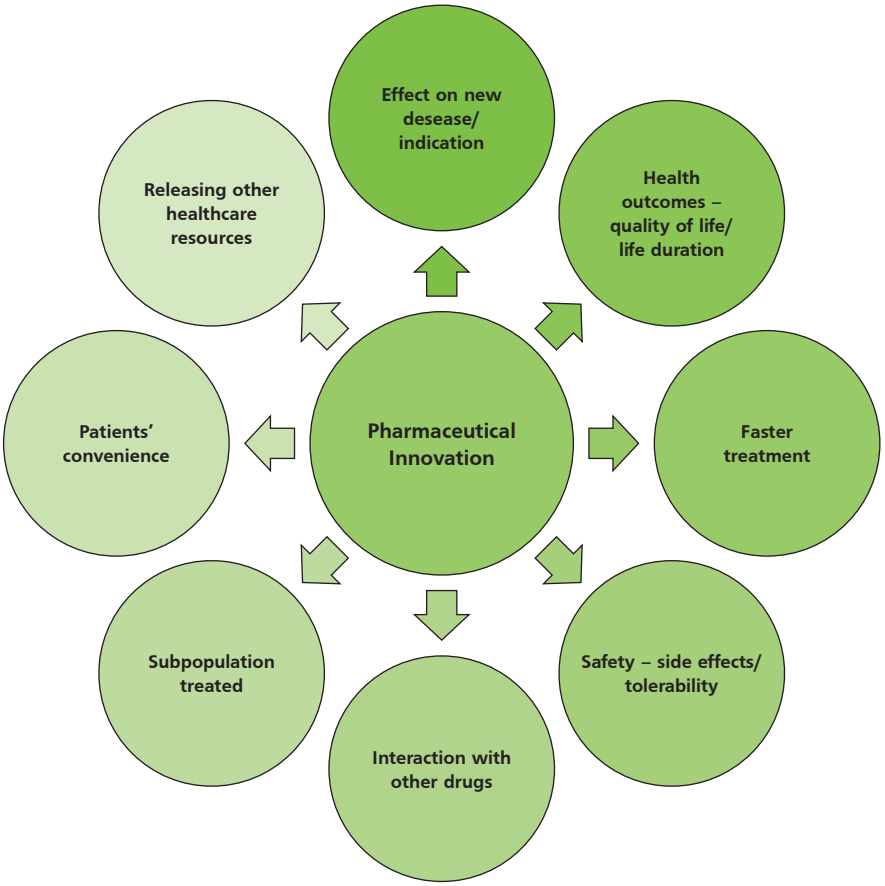
Furthermore, innovations are multidimensional and it is therefore misleading to try and assess innovation based on a single criterion. The position of the European Federation of Pharmaceutical Industries on this matter is that pharmaceutical innovation is not and should not be treated as 'black or white', a 'there or not' quality. **Each innovation in the pharmaceutical industry can improve the benefit-cost ratio in favour of the patient and/or have a positive outcome for the payer**.

Pharmaceutical innovation can be viewed from the perspective of three essential concepts:[63]

- Commercial concept – considers an innovation any newly marketed product (regardless of whether it is the first in its class), new substances, new indications, new formulations, and new treatment methods;
- Technological concept – refers to industrial innovation such as use of biotechnology or introduction of a new delivery system, or selection of an isomer or a metabolite;
- The concept of therapeutic advance – it concerns primarily professionals and means that a new treatment benefits patients when compared with existing options.

The innovation process in pharmaceutics involves serious investments and a long period of time. In order to identify a substance with the potential to become a drug, 5,000 to 10,000 chemical and biological compounds need to be tested. It is then necessary to invest in three to six years of extensive research to guarantee its safety and therapeutic efficacy, as well as another six to seven years of clinical trials. Each stage of the process carries a certain amount of risk.

FIGURE 65. CHARACTERISTICS OF PHARMACEUTICAL INNOVATIONS



Source: The Many Faces of Innovation by OHE Consulting for EFPIA, 18 February 2005.

BOX 7. PHARMACEUTICAL INNOVATIONS COST MORE AND TAKE MORE TIME

The increasing complexity of innovation is leading to higher R&D costs, higher regulatory hurdles, and longer product development times.

The focus on more complex diseases has led to significantly higher failure rate at all stages of R&D.

The average cost of developing new medicines has risen from over USD 800 million in 2000 to over USD 1.3 billion in 2011.

Source: Improving Global Health through Pharmaceutical Innovation, www.ifpma.org

[63] Kopp, Ch., "What Is a Truly Innovative Drug? New Definition from the International Society of Drug Bulletins", Canadian Family Physician, Vol. 48, September 2002, 1413-1415.

A close look at the innovation process in terms of the creation of a new drug identifies the following consecutive stages:

- Concept development;
- Preliminary market research;
- Project evaluation;
- Animal testing of new chemical compounds for biological activity;
- Human testing (phase I-III of clinical trials);
- Technological development of a dosage form;
- Development of effective manufacturing process;
- Filing an application for market authorisation;
- Mass production;
- Developing a detailed marketing plan;
- Marketing;
- Post-authorisation clinical trials (phase IV of clinical trials).[64]

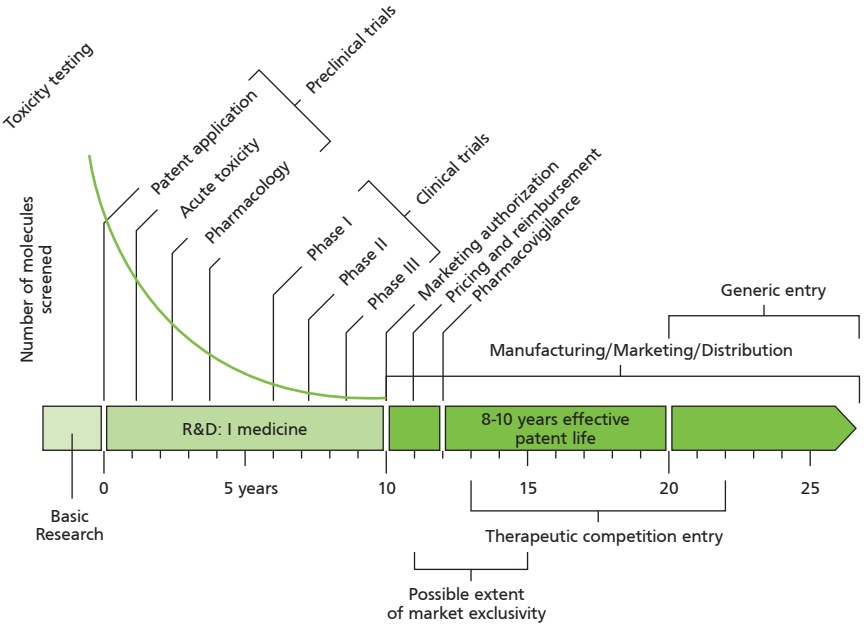
Up until the mid-1990s, most pharmaceutical innovations and their marketing were the work of a handful of pharmaceutical companies.[65] A common characteristic of the so-called R&D companies is their specialisation in building up structures which allow them to create and to introduce into medical practice various innovative products. At the same time, it is worth noting the ever increasing number of biopharmaceutical products developed both by big pharmaceutical companies and by research teams or biopharmaceutical.[66] The innovation practice of pharmaceutical companies confirms the existence of a correlation between company size and type of innovation – **the big companies are good at incremental innovations while the smaller firms are more effective in the field of radical innovations**.[67]

Drug manufacturers fall into two basic categories:

- **Brand developers** – they are engaged in research and development, handle the regulatory process of new products, including the clinical trials necessary for marketing authorisation, the production, marketing, and supply of innovative drugs.
- **Generic drug companies**, which can market generic versions of brand-name drugs once they come off patent or after the expiry of data exclusivity for the originator product.[68]

Such a distinction is rather general: a number of companies among those regarded as the leading innovators in the industry own subsidiaries which produce generic drugs. The opposite is also true – some typical generic drug companies have taken up innovative strategies in the past years.

Figure 66. STAGES IN THE PROCESS OF CREATING A PHARMACEUTICAL INNOVATION



Source: International Federation of Pharmaceutical Manufacturers & Associations (Adapted from Office of Fair Trading: The Pharmaceutical Price Regulation Scheme).

The generic drug companies are typically not considered innovators. Yet, many of them have become quite active in the field of innovation. The outcome is a **concentration of exclusive patent rights on a given medicinal product (concerning both the pharmaceutical substance and the form of the medication) in the hands of generic drug companies rather than those traditionally regarded as innovators**.[69] These efforts result in the creation of new improved products based on generic production.

In addition, some of the big generic drug companies are becoming actively engaged in the field of **biosimilar**

[64] Петрова, Г. и кол., Социална фармация и фармацевтично законодателство, Инфофарма ЕООД, 2010.

[65] Achilladelis, B., N. Antonakis, The Dynamics of Technological Innovation: The Case of the Pharmaceutical Industry, Research Policy 30 – 2001, www.elsevier.nl

[66] The Pharmaceutical Industry in Figures – Key Data, 2008 update – European Federation of Pharmaceutical Industries and Associations (EFPIA).

[67] Mazzucato, M., Fixing the Broken Innovation Model, Pharmaceutical Executive Digest Europe, Dec. 2009, 8-10, http://digital.findpharma.com/nxtbooks/advanstaruk/pee_digest_20091222/

[68] Idem.

[69] Ross, M. S., Innovation Strategies for Generic Drug Companies: Moving Into Supergenerics, IDrugs, 2010, Apr. 13(4):243-7.

medicinal products which may be regarded as innovative. Expanding the product range in this direction can be viewed as a long-term strategy aimed at securing sustainable access to the market.[70]

Historically there have been seven factors influencing the process of creation of technological innovations in the industry:

- Scientific and technological advancement (external to innovative companies);
- New raw materials (own and external);
- Market requirements;
- Competition in the industry;
- Societal needs;
- Legislative and regulatory requirements;
- Research, technological, and market specialisation of the company.

The first six factors can be defined as elements of the environment and affect similarly all innovative companies. The seventh one is specific to individual companies and has a significant influence on their policy over a long period of time. The intensity of these factors varies from one historical period to another. Furthermore, they tend to interact and have synergistic effects. Their influence largely determines the scope of the various technical and technological changes in quality and quantity of pharmaceutical innovations over the years.[71]

The past few years have been marked by a **slowing down and change in the direction of the innovation process in pharmaceutical companies**:

1) Since the beginning of the 1980s, the **Blockbuster model** has come to predominate among the big pharmaceutical companies regarding research and development and product marketing.[72]

The model essentially consists in identifying pharmaceutical substances that satisfy the unmet needs of a large number of consumers, their development with a suitable dosage form, and fast dissemination to target markets, as well as their aggressive marketing, largely through an extensive network of medical and sales representatives.[73] These products are provisionally known as 'blockbuster drugs' and reach annual sales of USD 1 billion; 'super-blockbusters' generate annual sales of USD 2 billion. There are about 100 products with the characteristics of blockbuster drugs, with only five of those qualified as super-blockbusters.[74]

The big pharmaceutical companies are reluctant to invest in research on diseases spread mainly in low and middle income countries where the markets are too small, the purchasing power of the population is not high, there is inadequate protection of intellectual property rights, and problems with the distribution.[75]

Analysts expect the current blockbuster model to deliver just a 5 % return on investment. This is considerably lower than the industry's risk-adjusted cost of capital. This suggests that only one out of six new drugs will deliver returns above their cost of capital which is an unattractive prospect for investors.[76]

2) The processes of consolidation, pricing pressure, and the need to set up marketing structures in new countries lead the big multinational pharmaceutical companies to concentrate on their own projects and product portfolios. While seeking blockbuster drugs in the most profitable therapeutic areas these companies tend to neglect various projects and products of medical value. This has opened up a market niche for a new type of pharmaceutical companies – the so-called 'specialty pharma', whose business concept is often based on aggressive use of existing opportunities for acquisition of products – from niche products to potential blockbusters.[77]

The term 'specialty pharma' is not clearly defined and covers a wide range of different approaches. The first wave of such companies focused on niche therapeutic areas. Gradually, there emerged a large group of companies, ranging from those concentrating on a specific therapeutic area to drug delivery experts and generic specialists.[78] In other words, the specialty pharma sector comprises three segments: generic drugs, drug delivery, and acquisition and licensing.

To the companies that adhere to this model it is particularly important to secure strong protection of intellec-

[70] Barei, F., C. Le Pen, St. Simoens, From Generic to Biosimilar Drugs: Why Take an Innovative Pace? Farmeconomia. Health Economics and Therapeutic Pathways, Vol. 13, No 3S, 2012, http://journals.edizioniseed.it/index.php/FE/article/view/328

[71] Achilladelis, B., N. Antonakis, The Dynamics of Technological Innovation: the Case of the Pharmaceutical Industry, Research Policy 30 – 2001, www.elsevier.nl

[72] Ferrara, J., "Personalized Medicine: Challenging Pharmaceutical and Diagnostic Company Business Models", MJM 2007 10(1):59-61.

[73] Nickisch, K., J. Greuel, K. Bode-Greuel, "How Can Pharmaceutical and Biotechnology Companies Maintain a High Profitability?", Journal of Commercial Biotechnology, Vol. 15, 4, 309-323.

[74] Mertens, G., "Beyond the Blockbuster Drug – Strategies for Nichebuster Drugs, Targeted Therapies and Personalized Medicine", Business Insights, 2005, 27; Liebman, M., Personalised Medicine – End of the Blockbuster?, http://www.pharmafocusasia.com/strategy/personalised_medicine_end_of_blockbuster.htm

[75] Dhanvijay, A., Open Source Drug Discovery (OSDD): A Paradigm Shift?, http://innovationandip.wordpress.com/2011/12/28/open-source-drug-discovery-osdd-a-paradigm-shift

[76] Thayer, A., "Blockbuster Model Breaking Down", Modern Drug Discovery, June 2004, 23-24.

[77] MEDA 2010 Annual Report, http://www.meda.se/fileadmin/uploads/MEDA_Corporate/pdf/MEDA_2010_Eng_webb.pdf

[78] Nickisch, K., J. Greuel, K. Bode-Greuel, "How Can Pharmaceutical and Biotechnology Companies Maintain a High Profitability?", Journal of Commercial Biotechnology, Vol. 15, 4, 309-323.

tual property rights regarding the technologies used to produce the newly created forms since these are far easier to circumvent than the patents on the active substance.

A number of projects associated with this business model are also supported by risk capital.[79]

3) **R&D outsourcing and cooperation** in the pharmaceutical industry

Over the past decade the pharmaceutical industry has been applying various types of tactics in order to overcome the problems faced in the creation of innovations – from increased spending on research in their own R&D departments, through horizontal consolidation, to obtaining licenses from the biotechnology sector. The process is characterised by ever increasing difficulties associated with coordination and managerial complexity and by attempts to implement increasingly complex and risky solutions. Yet none of these qualifies as 'panacea' for the slackening of the pace of innovation process in pharma.

One of the strategies publicly embraced by the big companies – **ever intensifying R&D outsourcing through cooperation with biotech companies, academic institutions or public-private partnerships** – looks quite promising. What underlies such collaboration is the rapidly developing concept of **open innovations in the pharmaceutical industry**.

There exist a host of reasons for pharmaceutical companies to **engage contractors for product development, its production, and the various promotional activities associated with its distribution**.

Above all, such collaboration secures a broader range of opportunities, specific expertise, and facilitated access to the market. Furthermore, it allows companies to reduce their initial capital expenditure, to restructure some of their fixed costs into variable ones, to make more efficient use of their resources, and generally enhance their own adaptability. Equally important is the possibility to expand their activity both with regard to new products and services and in terms of entry into new geographic markets without having to make additional megamergers (accompanied by enormous challenges) or to be swamped by corporate bureaucracy which all too often stifles innovation.

Essentially, the **outsourcing strategies of pharmaceutical companies involve engaging contract research organisations (CRO), contract manufacture organisations (CMO), and contract sales organisations (CSO).**

Pharmaceutical companies typically resort to the services of CROs at busy times when they cannot spare staff. In addition, CROs may be specialised in working in other countries, which matters greatly in international multicenter clinical trials.

At the same time, studies suggest that a pharmaceutical company conducting its own preclinical trial of a new drug is likely to incur costs twice as high than if it were to hire contractors. Moreover, CROs are known to reduce the time it takes for a new drug to gain access to the market. When conducting multinational, multicenter research the time necessary for clinical trials is on average more than 30 % shorter if using the services of a contractor. Sponsors typically need 88 weeks to complete phase I of a clinical trial, whereas contract research organisations, 66 weeks. In phase II, the average duration is 139 weeks for the sponsor and 81 weeks for the CRO, and in phase III, 140 and 97 weeks, respectively.[80]

4) **Public-private partnerships** (PPP) have great potential in terms of furthering the development of key sectors such as education and healthcare by enhancing efficiency and improving the quality of innovations in public services.[81]

There has been significant headway in the area of public-private partnerships and more specifically, partnerships for the development of a particular product. PPP with a focus on tuberculosis, malaria, and the neglected tropical diseases, as well as the diagnostics of tropical diseases, have been very successful. They, however, are faced with a number of challenges, including the timeframe of financing – it is usually shorter than the time it takes to create a new product or diagnostics method. For this reason it is necessary to identify the most successful models of cooperation and to achieve better understanding of the most important indicators of successful partnership.

5) Historically, the pharmaceutical industry has been organised as a closed model where a single company has all the means and resources to pursue its goals – from the conceptual stage to the marketing of a new drug, all while keeping all intellectual property rights within the company. The model of **open innovation** is associated with a far more dynamic ecosystem, and the borders of the organisation become considerably more permeable.

[79] Nickisch, K., J. Greuel, K. Bode-Greuel, "How Can Pharmaceutical and Biotechnology Companies Maintain a High Profitability?", Journal of Commercial Biotechnology, Vol. 15, 4, 309-323.

[80] Pharmaceutical Outsourcing Strategies – Market Expansion, Offshoring and Strategic Management in the CRO and CMO Marketplace, Bisness Inside, 2005.

[81] Министерство на икономиката и енергетиката, Глобален иновационен индекс 2012 г. Глобален растеж чрез иновационно сътрудничество, 2013.

Innovation potential of the pharmaceutical industry in Bulgaria

Fundamental research in the pharmaceutical area requires intensified interaction between science, education and business, which is non-existent in Bulgaria. In fact, very few countries in the world manage to achieve effective interaction in this area. Europe has been trying to attract research potential to the pharmaceutical industry but can hardly cope with the competition of USA and Japan. Only the largest domestic markets within the EU (Germany, France) qualify as attractive in this respect.

In Bulgaria there is a combination of a very limited, tightly regulated market and the lowest prices of medicines in the EU. Numerous regulatory obstacles all too often impede the implementation of pharmaceutical research in the country. Of the various stages and components of research and innovation in the pharmaceutical industry, what is being **implemented in Bulgaria is largely clinical testing** and the establishment of certain medications (including by granting production and distribution authorisations) already well-known in the world market. Even with respect to clinical trials, there is no adequate R&D infrastructure in Bulgaria. Clinical testing in Bulgaria is largely commissioned by the companies which are members of the Association of Research and Development Pharmaceutical Companies (ARPharm).

In this sense, **Bulgaria can seek competitive advantages in the following directions**:

- Production of **hard-to-make-generics** (innovation with respect to the form of the medication) since this segment is not of interest to the large-scale manufactures in China and India (of tablet forms, for example);
- Facilitating the **involvement of SME research**, including through the European Innovative Medicines Initiative;
- As a **leader in generics production in the region**. The generic companies in Bulgaria have a capacity far exceeding the potential of the domestic market;
- Bulgaria can hardly expect to gain a leading position in the creation of new medicinal substances and the industrial synthesis of active and excipient ingredients for the pharmaceutical industry. Notwithstanding, **investment in the isolation of biologically active substances of plant and animal origin may prove a winning strategy**.
- **The strategy of outsourcing activities to contractors adopted by the big multinational companies provides an opportunity for the domestic industry**.

There are cases in point, as well as examples of attracting foreign investments and setting up subsidiaries of regional and European importance. These processes need to be actively encouraged and supported by the government.

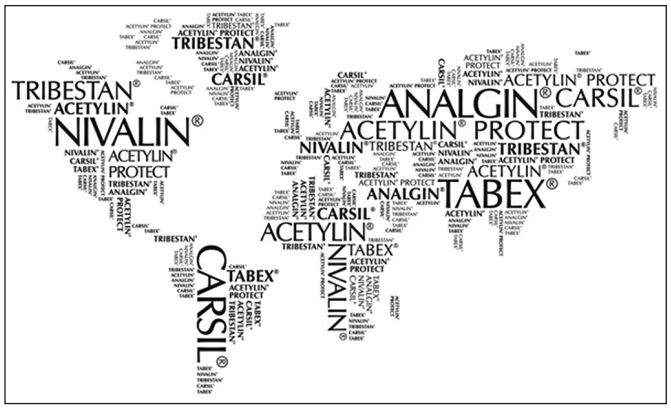
The market entry strategies of international pharmaceutical companies in Bulgaria vary widely both by preferred form of business organisation (subsidiaries, branches, commercial representative offices, joint ventures) and by their role in the value-added chain. The main tasks of these companies are related to the marketing and sale of medicinal products, as well as to administrative support in product registration and in meeting other regulatory requirements. There are occasional instances of involvement in research and the production process.

Box 8. SOPHARMA: THE LONG ROAD FROM COOPERATIVE LABORATORY TO MULTINATIONAL COMPANY, 1933 – 2013

The history of present-day Sopharma AD began back in 1933 when the Bulgarian Pharmacy Cooperative started the construction of the first medicinal production laboratory. In 1942, the laboratory moved and expanded into the Galenus factory which was nationalised in 1953 and served as the basis for the Chemical-pharmaceutical plant – the predecessor of Sopharma. Already in the 1940s, the Galenus factory established itself not only as the first modern pharmaceutical plant in the Balkans but also as a successful competitor to Swiss and German firms. In 2000, the company was privatised and listed on the Sofia Stock Exchange and since 2011 has been listed on the Warsaw Stock Exchange, as well. Although its listing in Warsaw has not increased its capitalisation dramatically, the fact that there is already a Bulgarian company listed on a foreign stock exchange, moreover among the most important ones in Eastern Europe, indicates the tendency for Bulgarian firms to position themselves and to act as multinational companies. Further evidence of the good prospects of Sopharma is found in the fact that its shares have been included in a number of stock-market indices.

Production by Sopharma develops in 7 main areas: manufacture of medicines; substances and preparations based on plant raw materials (phytochemical production); veterinary vaccines; infusion solutions; haemodialysis concentrates; medical devices and products for human and veterinary medicine; injection and blow molded products for industry, agriculture, and household use.

Box 8. SOPHARMA: THE LONG ROAD FROM COOPERATIVE LABORATORY TO MULTINATIONAL COMPANY, 1933 – 2013 (CONTINUED)



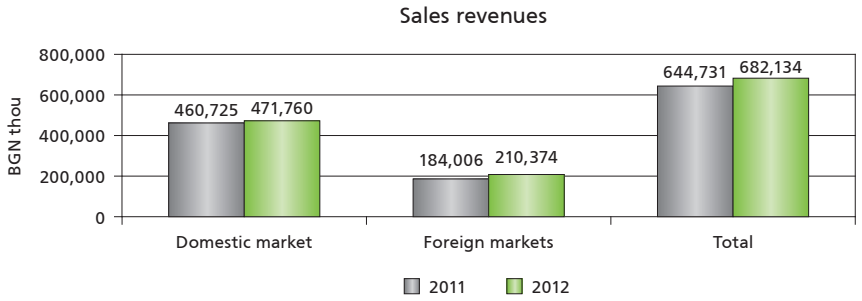
Sopharma owes its leading position both to the production of lower-priced generics and to considerable R&D activity. Sopharma R&D staff have authored independent and joint publications with medical scientists from Bulgaria and abroad. The reputed scientific database Scopus includes 12 scientific papers with co-authors working at Sopharma. A far larger number of publications by researchers from leading UK and US universities have been based on R&D of Sopharma companies in these two countries. 10 % of all patents registered in Bulgaria in 2001 – 2011 are owned by Sopharma, making it the undisputed leader in patenting and the market establishment of own products. Fifteen out of 210 products in the Sopharma portfolio are originator ones. One of the most successful ones is Tabex, produced since 1964, which helps users give up smoking and has been the reason for investments in US and UK (obligatory clinical studies prior to marketing). The originator product Carsil (plant-based, for the treatment of gastroenterological disorders) and Tempalgin (an original analgesic) account for the larger portion of export revenues. In 2012, Sopharma introduced three new products. In 2013, 3-5 new products are expected to be launched and in the next few years, Sopharma will strive to bring product innovations up to about 10 on an annual basis. The new products are associated with great many process innovations. As of the beginning of 2013, Sopharma estimated their number at about 50 production processes and technologies (which are in the process of transfer and optimisation). By these quantity indicators, Sopharma certainly ranks among the innovation leaders in Bulgaria.

At present, in addition to 12 plants in Bulgaria, Sopharma has two production facilities in Serbia and one in Ukraine. The latter have R&D departments, with the one in Serbia employing 7-8 people engaged in clinical trials and studies. In 2012, Sopharma parted with its ten-year 51 % ownership of the production company ZAO Rosbalkanpharm (Russia). One of the reasons for this decision were the administrative obstacles to its business operations encountered already in 2011, but also the subsequent legislative amendments in 2012 which gravely impeded Sopharma's operations in Russia, namely, the newly introduced requirement for generic analgesics to be available by prescription only. Sopharma's best-selling product in the Russian market was the analgesic Sedal M, which by Sopharma data had been among the top 3 pharmaceutical products in Russia. Other Bulgarian companies have lately been faced with similar problems (since the increase in import duties on Bulgarian cosmetics).

Sopharma has subsidiary companies in the USA (Sopharma USA, 100 % owned by Sopharma AD, Extab Corporation, 80 % owned by Sopharma AD, engaged in clinical trials and studies); in the UK (Extab Pharma Ltd., clinical trials and studies, 80 % indirect control by Sopharma AD); Poland (Sopharma Warsaw Ltd), Serbia (Ivancic and Sons production company), Ukraine (Sopharma Ukraine and Vitamini production company – 99.56 %), Latvia (Briz Ltd, 51 %), Belarus (shares in a number of pharmacy chains acquired through its subsidiary Briz Ltd, which has thus become the third largest private pharmacy chain in Belarus; the companies in which Sopharma has invested include Brititrade, Tabina, Brizpharm, Allanko, Interpharm, Vivaton). Certain Sopharma drugs are licensed for production in Vietnam. The company counts on its Briz subsidiary to implement its strategy for entry into the Scandinavian markets.

In many respects Sopharma AD qualifies as a multinational company – it has production facilities in more than one country (three, and if the ten years in Russia are counted, four); has made investments in a number of countries (in the US and UK – in business operations and in R&D, as well as vertical integration, most notably in Belarus) and is selling its products in more than 70 countries; is listed on the stock exchange (moreover, on a foreign one in addition to the Bulgarian stock exchange), and has a changeable shareholder base. Furthermore, Sopharma is active in the merger and acquisitions market (Bulgarska Roza – Sevtopolis, Unipharm, Medica, RDCPI – in Sopharma; and Sanita Trading, Kaliman, Global Medical, Consumpharm, Elpharma – in Sopharma Trading), including portfolio investments (with its investment in Lavena, Sopharma entered the cosmetics market and became a major distributor of Lavena in Bulgaria, through Sopharma Trading, and abroad, through its other companies), at this stage mainly in Bulgaria and Belarus (pharmacies), but most probably in new markets as well.

Box 8. SOPHARMA: THE LONG ROAD FROM COOPERATIVE LABORATORY TO MULTINATIONAL COMPANY, 1933 – 2013 (CONTINUED)



However, Sopharma revenues are still largely generated in Bulgaria. In 2012, export revenues only amounted to 31 % of the total. Sopharma holds a mere 5 % share of the Bulgarian pharmaceutical market, while Sopharma Trading has a 21.6 % share of the distribution market, followed closely by Phoenix/Libra with 20.4 % and Sting with 20.6 %. Even though it is one of the major Bulgarian companies with a turnover of BGN 682 mln (in 2012), about 4,000 employees in the group as a whole and a significant international presence, Sopharma is still a small, niche player on the global scale. Yet, its activity to date provides serious indications of its potential to become a global competitor, particularly in the developing markets.

Source: Sopharma, 2013.

Investments and human resources for research and innovation

The entry into the pharmaceutical market implies significant investment in building the necessary research and production capacity and developing a distribution network to sell the product portfolio. Furthermore, the development of a new product always necessitates special material and intellectual resources, including a highly qualified workforce. A serious presence in the pharmaceutical market requires a well-developed distribution system, including a team of a large number of qualified specialists to present and promote the new pharmaceutical products among doctors and medical specialists.

Although the driving force of the pharmaceutical industry is innovation, companies invest significant funds in marketing.[82] The **largest R&D companies invest on average about 16** % (and more by specialty pharma) **of their revenues in research and development and 26** % **and more in activities related to marketing and sales**.[83]

Approximately 90 % of the funds allocated to marketing are targeted at the prescribing doctors, which clearly reveals the industry's priority methods for shaping the pharmaceutical market.[84]

Regardless of the fact that the appearance of almost every new drug is qualified as a 'wonder' by the general public, this is still not enough for companies to recover the costs incurred in its development and actually make a profit.[85] They need to employ specific business knowledge and skills, especially given the context of a tightly regulated market. They need to produce sufficient evidence to convince the payers in healthcare of the need to finance, and the prescribing doctors to choose the specific product, which is usually therapeutically quite close to other medicines already available in the market. Furthermore, it is necessary to take under consideration the specific conditions and characteristics of the logistical chain of medicinal products in the different markets. Pharmaceutical manufacturers adopt different strategies to cope with these challenges.

The big pharmaceutical manufacturers in Bulgaria spend a small share of their annual turnover on R&D. Thus, for instance, R&D spending of the foreign-owned company Actavis and the Bulgarian Sopharma is **in the range of 5** % of annual sales revenues. For the major manufacturers of generics in the country, the typical annual R&D budget amounts to BGN 1-2 million, compared to the billions spent on R&D by the leading multinational corporations in the pharmaceutical industry.[86]

The common problems of the national innovation system regarding R&D financing – lack of coherent priorities along the science-technologies-economy chain; lack of long-

[82] Lui, Q., The Dynamics of Competitive Drug Detailing. The Johnson School at Cornell University, 2007.

[83] Kesič, D., Dynamic Development of World Pharmaceutical Market, 22nd of May 2006, Delo, Ljubljana, p. 12.

[84] Blumenthal, D., Doctors and Drug Companies. Engl, N., J. Med, 2004; 351:1885, Brennan, T. A., D. J. Rothman, L. Blank, D. Blumenthal, S. C. Chimonas, J. J. Cohen, J. Goldman, J. P. Kassirer, H. Kimball, J. Naughton, N. Smelser, "Health Industry Practices that Create Conflicts of Interest: A Policy Proposal for Academic Medical Centers", JAMA, 2006; 295(4):429-433.

[85] The Pharmaceutical Innovation Platform – Sustaining Better Health for Patients Worldwide – IFPMA (International Federation of Pharmaceutical Manufacturers & Associations), Geneva, Switzerland, 2004.

[86] World Bank, Input for Bulgaria's Research and Innovation Strategies for Smart Specialization, February 2013.

term vision and sustainable horizon of financing; lack of transparent procedures for distribution of public funds and for monitoring and assessment of their spending; corrupt practices – also apply to the insufficient and inadequate financing of the related areas of medicine, pharmacy, and healthcare:

- In the past three years, the **medical sciences have been an outstanding priority in terms of allocated financing, yet this does not apply to the staff engaged in R&D,** in the medical sector, nor to the number of articles in international referenced publications. Healthcare is the education area that only comes fifth by graduation rates at the three levels of higher education (see more in the Research Product section of this report).
- **Budget spending on healthcare is chaotic** (see more in the Investment and Financing for Innovation section of this report).
- According to experts, **Bulgarian organisations do not seem to manage to participate effectively with their own projects in the distribution of European public funds for research and development in the pharmaceutical area**.

After the first five sessions of the National Innovation Fund, 22 projects (or 5.8 % of all financed projects) have been in pharmaceutics out of 20 thematic areas. Their number was highest (16), and respectively so was their share in the total number of projects (14.8 %), in the third session of the Fund in 2006.

The pharmaceutical industry and the related sectors along the value added chain in Bulgaria generate the largest number of qualified jobs, of which roughly 3,000 in the area of R&D with a noticeable trend towards increasing employment in the area of clinical trials. A large number of the researchers work for private laboratories and are engaged in clinical trials whose number has increased on account of outsourcing to Bulgaria by the big multinational companies. The results of the studies are not always applied by the local R&D laboratories, which have limited staff and are primarily involved in the administration of clinical trials.[87]

Patent legislation in the area of pharmaceutics

Patent legislation is one of the crucial factors influencing pharmaceutical companies' decisions to invest in specific countries. In this respect, there has been a marked tendency towards amendment of the existing legislation both in traditional pharmaceutical markets and developing ones – India, China.

Intellectual property rights are a key element in encouraging innovation. Their protection matters to all economic sectors and is of primary importance to competitiveness in Europe. It is particularly important in the pharmaceutical sector in view of the need to address existing and arising health problems and the long life cycle of the products (including the long product development phase). Some of the largest investments in R&D in Europe have been made in the EU pharmaceutical industry which largely relies on intellectual property rights to protect innovations. The term of exclusive rights granted under the existing patent legislation and other mechanisms (additional protection certificates, data exclusivity) provides incentives to originator companies to pursue innovation.

At the same time, public budgets, including healthcare budgets are under great strain and limitations. Competition, particularly from generic medicines, is of great significance for managing public budgets and ensuring the broad access of consumers/patients to medications.[88] The main conflict between the two types of pharmaceutical industries in Europe and the world arises out of the increasing pressure to extend the term of protection of originator drugs and the opposing but equally strong demand for speedier market entry of generic drugs.[89]

Since 1980, the EU has repeatedly increased the intellectual property protection of pharmaceutical products. It prides itself on the highest degree of intellectual protection of medicinal products in the world, comprising:

- Patents for high-tech products;
- 20-year product patents;
- Certificate of additional protection of a medicinal product extending the 20-year term for up to 5 more years;
- Patents for the methods of obtaining a substance, indications, dosage, substance, product composition, changes in formulation, use.

Since 1990 the number of patentable medicinal properties and characteristics has increased. In the 1980s, there were only 5 patentable characteristics: first use; process and intermediate products; bulk form; dosage form; composition. In the 1990s, the number of patentable medicinal properties grew to 18: first use; process and intermediate products; bulk form; dosage form; composition; indications; method of treatment; mechanism of action; packaging; delivery; dosage regimen; dosage regimen; dosage method; combinations; method of observation; chemical methods; biological ideas; field of use.[90]

[87] World Bank, *Going for Smart Growth: How Research and Innovations Can Work for Bulgaria*. Report. No. 66263-BG, 2012.

[88] European Commission, *Pharmaceutical Sector Inquiry Report*, 2009.

[89] Едно горчиво хапче за преглъщане – 10 мита за иновативната фармацевтична индустрия, Фармацевтичен бюлетин, бр. 3, 2004.

[90] http://www.bgpharma.bg/bulletin/read/edition/8/content/article_46_print.html

In the industry, patents for active ingredients are known as **'primary patents'** since these are the first patent applications filed for the product. The subsequent patents for different aspects such as physical form, production process, or special pharmaceutical formulations are called **'secondary patents'** in the industry. Patent law makes no distinction between primary and secondary patents and they should be evaluated in terms of the legally established criteria for patentable subject matter rather than the stage at which the applications were filed. The term 'secondary patent' therefore should not be taken to imply inferior quality or value but simply that it chronologically comes after the primary patent.[91]

In addition to patent protection, originator pharmaceutical companies in the EU can take advantage of a period of data exclusivity.[92] The provisions on data exclusivity were introduced into European legislation in 1987 in order to compensate for the absence at the time of a legal framework for biotech products and to protect them from generic copies for a period of 10 years. This gap in European legislation was filled in 1999, yet the provisions on data exclusivity have remained in force.[93]

The new EU regulations adopted in 2004 created a harmonised European framework for data exclusivity.[94] It establishes the procedures for filing the so-called 'dependent' applications, when the market authorisation applicant does not provide the data from pharmacological, toxicity tests and clinical trials, the so-called part III and IV of the documentation – the most time-consuming and costly part of application preparation.

Data exclusivity is not a continuation of patent rights. Patent rights and data exclusivity are different concepts, protect different rights, stemming from different efforts, and have different legal implications at different times.[95]

Because of the significance of a well-functioning pharmaceutical sector and the existence of some indications of restricted competition in the EU pharmaceutical market, on 15 January 2008 the EC began a sector-specific inquiry. Its goals were to examine the reasons for the delays in generic market entry and for the conspicuous decline in innovation, as measured by the new drugs introduced into the market.

According to the conclusions of the inquiry,[96] **in the past years, originator companies have changed their patent strategies**. Strategic documents of originator companies provide confirmation that some of them develop strategies to extend the scope and duration of their patent protection. It is common practice to file multiple patent applications for the same drug (forming the so-called 'patent clusters' or 'patent thickets'). The documents collected in the course of the inquiry confirm that **one important goal of this strategy is to delay or block the market entry of generic drugs**.

Another instrument employed by the originator companies is filing **voluntary divisional applications**, largely before the EPO, where most patent applications in the pharmaceutical industry are filed.

The conclusions of the inquiry show that for 40 % of the drugs included in the in-depth study sample and which had lost their exclusive rights in the period 2000 – 2007, the originator companies had released second-generation drugs in the market. Close to 60 % of the cases of patent litigation between originator and generic drug companies examined in the context of the inquiry were found to involve a shift from first to second generation drugs.

Patents and other strategies/instruments are sometimes used cumulatively **in order to extend the life cycle of drugs**. The extent to which companies resort to such means depends on the commercial importance of the particular drugs.

Patent activity in Bulgaria

Close to one-fifth of the patents granted in the period 2001 – 2012 in Bulgaria were in the pharmaceutical sector – 2,178 (18.3 %). Bulgarian patent presence for the period as a whole was quite insignificant (4.4 %) compared to the predominantly foreign one – 95.6 %. Among Bulgarian owned patents, the share of pharmaceutical ones is 8.3 % and among foreign owned patents, 18.7 % are pharma patents.

The overall patent activity in Bulgaria in the pharmaceutical sector is largely determined by the foreign patent presence, with its share displaying a rising trend – from 75.9 % in 2001, to 98.7 % in 2012. The reverse tendency is observed among Bulgarian owned patents – from 24.1 % in 2001 down to 1.3 % in 2012.

In the last five-year period (2008 – 2012), Bulgarian patent owners were granted a total of 44 patents in the pharmaceutical sector – barely 2.8 % of all pharmaceutical patents. The remaining 97.2 % are owned by foreign companies. Within the institutional structure of these patent owners, business entities are represented with 25 patents (56.8 %), 31.8 % have been granted to individuals, and public sector organisations hold

[91] European Commission, *Pharmaceutical Sector Inquiry Report*, 2009.

[92] http://198.170.119.137/gen-dataex.htm

[93] www.mee.government.bg/doc_pub/pharmacia.pdf

[94] http://198.170.119.137/gen-dataex.htm

[95] Data Exclusivity: Encouraging Development of New Medicines – June 2011 IFPMA, http://www.ifpma.org/fileadmin/content/Publication/IFPMA_2011_Data_Exclusivity__En_Web.pdf

[96] European Commission, *Pharmaceutical Sector Inquiry Report*, 2009.

Table 19. STRUCTURE OF PATENTS GRANTED IN BULGARIA IN THE PHARMACEUTICAL SECTOR, NUMBER*

	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	Total
Bulgarian owners	14	14	7	3	4	6	3	8	20	7	4	5	**95**
Foreign owners	44	27	21	32	63	158	206	267	278	303	290	394	**2,083**
Total	**58**	**41**	**28**	**35**	**67**	**164**	**209**	**275**	**298**	**310**	**294**	**399**	**2,178**

* Section 21 of NACE-2008, Classification index under IPC – A61K, Preparations for medical, dental, or toilet purposes.

Source: Compiled by data from the Official Bulletin of the Patent Office of the Republic of Bulgaria, 2013.

merely 5 patents (11.4 %). Higher education institutions have not been granted any pharmaceutical patents in this period.

In the period 2008 – 2012, patents were granted in Bulgaria to owners from 79 foreign countries. Of those, the patents of 49 countries (60.8 % or 1,550 patents) were in the pharmaceutical sector. With some inconsequential differences, the rankings of the top 15 by general patent activity and by patents in the pharmaceutical sector overlap by 90 %.

The structure of foreign patent activity provides important indications of the technological specialisation of the different countries and their intentions in a given market. Thus, for instance, out of the total number of patents issued in Bulgaria to Irish companies, 49.1 % pertain to the pharmaceutical sector. For Luxembourg the respective share is 40.0 %, Japan, 27.0 %, USA, 26.0 %. For Sweden, France, Spain, Belgium, Italy, and Switzerland the share of pharmaceutical patents in the total number of patents granted for the respective country ranges between 22.7 and 19.3 %.

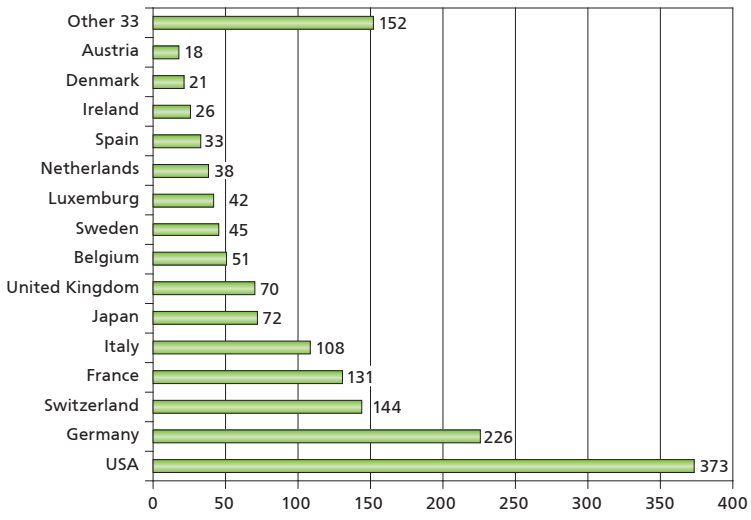
In the period 2008 – 2012, 65.7 % of the foreign owners of pharmaceutical patents granted in Bulgaria were companies from European countries; 24.1 %, from the USA; 4.6 %, from Japan; and 5.6 %, from other countries. US companies have the most marked presence with increasing activity throughout the period.

Table 20. BULGARIAN PHARMACEUTICAL PATENT OWNERS IN THE PERIOD 2008 – 2012

№ by order	Patent owner	Number	%
1	Sopharma AD, Sofia	19	43.2
2	Unipharm EAD, Sofia	2	4.5
3	Agricultural Institute, Shumen	2	4.5
4	Ministry of Defence, Sofia	2	4.5
5	Biopharm Impex – Ivanov & Co, Sofia	1	2.3
6	Laktina OOD, Sofia	1	2.3
7	Adipharm EAD, Sofia	1	2.3
8	VEMO-99 EOOD, Botevgrad	1	2.3
9	Military Medical Academy – Sofia	1	2.3
10	Individuals	14	31.8
	Total	**44**	**100.0**

Source: Compiled by data from the Official Bulletin of the Patent Office of the Republic of Bulgaria, 2013.

Figure 67. TOP 15 COUNTRIES BY PATENT ACTIVITY IN BULGARIA IN 2008 – 2012 IN THE PHARMACEUTICAL SECTOR, NUMBER OF PATENTS



Source: Compiled by data from the Official Bulletin of the Patent Office of the Republic of Bulgaria, 2013.

Box 9. A BULGARIAN INVENTION OF IMPORTANCE TO PULMONARY DISEASE DIAGNOSIS AND CONTROL

In 2000, three independent teams: Paredi and associates in London; Piacentini and associates in Verona, and Todor Popov and associates in Sofia, began measuring the exhaled breath temperature (EBT) in asthma patients. Their assumption was that tissue vascularisation and temperature rise in the process of inflammation, which is nowadays believed to be the hallmark of asthma. Both teams in London and Verona used fast-reacting thermocouples in front of the mouths of the subjects and analysed the computer-recorded rise in temperature during single-breath manoeuvres. This required sealed laboratory environment with constant temperature, minimal air movement, and subject training to allow the record of comparable exhaled breath temperature curves. While the London team considered the rate of increase in EBT as indicative of asthma, the researchers in Verona conducted a series of tests demonstrating that the peak of the EBT curve is the variable distinguishing asthma patients from the healthy controlled subjects.

The Bulgarian team invented a simple, handheld instrument for EBT measurement which makes the evaluation process less dependent on ambient factors and allows individual home measurement in patients needing daily/frequent monitoring.

Prof. Todor Popov: "As incredible as it may sound, nobody had measured EBT. There was a wide gap in the map of human physiology".

The idea underlying the EBT device was to accumulate the thermal energy of the exhaled air of a tested subject into an insulated vessel containing a chamber with a thermal core. After numerous experiments and tests, an **EBT measurement instrument (X-halo) was developed that combined ergonomic design with easy-to-use microprocessor controls and built-in memory**.

Prof. Todor Popov: "One of the crucial questions we were faced with at the outset of our work was whether EBT was only a surrogate measure of body temperature and whether it captured the signals of the respiratory system. Another important issue was whether changes in ambient factors such as temperature, humidity, pressure, etc., would affect EBT measurement. EBT proved an unexplored territory on the map of human physiology and pathophysiology. Now we have the opportunity to fill in the gaps with the help of this straightforward and inexpensive method. Findings regarding its uses for other diseases and conditions are yet to be published. Our portable device facilitates the application of the method in daily clinical practice since it even allows individual home measurements. The capacity of the fifth-generation device to conduct and record multiple measurements is of great value to clinicians in monitoring and managing asthma exacerbations".

The X-halo device has been **patented in 57 countries, including EU, USA, Russia, Japan, and others. It is manufactured by the Singapore based company Delmedica Investments LTD** (www.x-halo.com).

Source: Кралимаркова, Т., В. Димитров, Т. Попов, Температура на издишания въздух – нов маркер за оценка на дихателните пътища, Клиника по алергология и астма към УМБАЛ „Александровска", София, сп. „Торакална медицина", т. I, декември 2009, бр. 2, www.x-halo.com

European and national policies supporting the innovation potential of the pharmaceutical industry

The pharmaceutical industry is acquiring increasing global dimensions. This process presents European pharmaceutical companies with opportunities for entry into new markets. At the same time, the **EU has begun to fall behind in the area of pharmaceutical innovation**. R&D investments are gradually shifting from Europe to USA and Asia, although there have been indications of reversal in this tendency in the past year. At the same time, global cooperation and trade are leading to global labour segmentation and diversification of the countries where the various stages of the innovation process take place. This global reorganisation creates opportunities but poses new challenges as well, particularly with respect to the increasing number of false drugs.

Some of the factors affecting the development of the pharmaceutical industry are sector-specific and others are related to broader areas such as fiscal policy, labour costs, education, and training. **Regulations entailing a greater administrative burden without providing tangible public health benefits have a strong adverse im-**

pact on the EU industry's competitiveness. Particularly affected economically are SMEs – for instance in the area of pharmaceutical control (excessive reporting requirements in some member countries entail unwarranted costs). Such obstacles can prove decisive in driving companies to give up applying for authorisations in markets other than their country of origin.

In addition to the widespread perception that the R&D model in the pharmaceutical industry is ineffective and is not producing enough innovative molecules, in the 1990s in Europe the opinion arose that the European pharmaceutical industry is outperformed by the U.S. This found further confirmation in the report published in 2000 and entitled *Global Competitiveness in Pharmaceuticals – A European Perspective*. A subsequent report in 2007 provided evidence of loss of competitive advantages in the biotech industry as well. In 2011, a new study confirmed that, **notwithstanding increasing investments in research in the industry in the past decades, there has not been any increase in the number of approved new drugs or more substantial progress in coping with the challenges of therapeutic practice**.

The main financial resource within the EU for the development of research in areas related to the pharmaceutical industry, medicine, and healthcare is distributed through the framework programmes for scientific research and technological development. In the period 2002 – 2006, EUR 2.5 billion were allocated through the Sixth Framework Programme for the thematic area "Life sciences, genomics, and biotechnology for health". In the Seventh Framework Programme, the budget for health-related activities amounted to EUR 6 billion.

The **Innovative Medicines Initiative** launched in 2008 and with a total budget of EUR 2 billion up to 2013 was a key measure to enhance European competitiveness in R&D in the biopharmaceutical sector. The goal of this **new instrument for public-private partnership between the industry and EC** was to improve and step up the development of drugs and provision of new treatment opportunities for patients.[97]

Innovations cannot take place in the absence of a number of prerequisites such as political and financial stability and a regulatory framework protecting and encouraging innovations. The chief **factors promoting pharmaceutical innovation with a focus on public health benefits** include:

- **The presence of a successful healthcare system.** On the one hand, the healthcare system regulates the provision, prescription, payment, and reimbursement of medicinal products and on the other, constantly stimulates the innovation process;
- **(Un)predictability of regulatory decision-making** on access to the markets of EU member countries, on new medicinal products and the processes of pricing and reimbursement of medicines;
- **Protection of intellectual property rights** which have been posing additional barriers to innovation in the past decade;
- **(Im)provident policy of European regulatory bodies** which in the past years have been driving manufacturers to reduce prices of medicinal products without consideration for the devastating effect on the R&D budgets of pharmaceutical companies and without providing the much needed support for research projects.

As a result of the war on high prices which was launched with the aim of reducing healthcare spending, the prices of the latest innovative medicines in a given therapeutic class are often close to those of the generic ones. For this reason, **in the past years, the European pharmaceutical market has lost a great deal of its appeal and when planning production costs manufacturers of innovative medicinal products increasingly tend to prefer USA and Asian countries**.

European institutions are faced with a grave choice that will determine the future of the pharmaceutical industry in Europe. It is necessitated by the fact that, in the past decade, income per capita in the EU has begun to decline compared to the United States, even accounting for the statistical effect of EU enlargement. Combined with the problem of an ageing population, this makes it all the more critical to undertake measures to reduce healthcare costs. Such measures are mainly related to providing **incentives for the domestic generic industry by introducing elements of internal referencing and/or generic substitution and reducing the profits of innovative manufacturers**. These are accompanied by **slower market entry of innovative therapies** in the member countries.

Generic drugs have a substantial contribution towards the sustainability of health systems in Europe. Furthermore, generic drug production is important to the economy and employment on the continent. On a European scale, generic manufacturers provide over 150,000 jobs and help achieve savings amounting to more than EUR 35 billion per year, and in addition, generic and biosimilar medicines facilitate patients' access to quality and affordable treatment.

[97] Kaplan, W., V. Wirtz, A. Mantel-Teewuisse, P. Stolk, B. Duthey, R. Laing, Priority Medicines for Europe and the World 2013 Update, World Health Organization, July 2013, http://www.who.int/medicines/areas/priority_medicines/MasterDocJune28_FINAL_Web.pdf

The ineffective medication policy and regulatory framework which deepen the problems with access to generic drugs within the EU, including Bulgaria, are associated with the following:

- Lack of sufficient financial resources to meet the demand;
- Lack of information transparency regarding public spending;
- Lack of incentives for the demand and efficient use of generic drugs;
- Lack of incentives with regard to the supply, market entry of new generic drugs, and the competition;
- Adoption of measures to reduce prices along the supply chain;
- Lack of unregulated pricing even for drugs which are not reimbursed by the national health system;
- Internal price referencing with the lowest prices among EU countries, in the case of Bulgaria;
- Internal reference pricing within therapeutic groups leading to downward spiralling price competition;
- Low reimbursement rates (25 % for socially significant diseases for Bulgaria) which increase the costs for patients.

In early 2012, the EC made its recommendations regarding changes in the **Transparency Directive which are directly aimed at ensuring speedier patient access to generic medicines**. According to the EC, the Transparency Directive should guarantee:

1) Introduction of a 30-day price and reimbursement approval time-limit for generic medicines – this will help to maximise potential savings to patients and the healthcare sector, whilst increasing affordability, patient access and health budget control.
2) Putting an end to patent linkage which links the approval of the price and reimbursement of generic medicines to the patent status of the originator reference product – this will foster a competitive market by speeding up the entry of generic medicines onto the market, thereby realising savings and creating access to affordable treatments. This is in line with jurisprudence in various member states that ruled against patent linkage in the price and reimbursement process.
3) Eradicating double bioequivalence assessment by pricing and reimbursement authorities where the reference product has already been in the market place for several years. This will help overcome the delayed market entry of generic medicines.

In order to enhance the efficiency of their medicine markets, to optimise public health services, and reduce expenditures in their health budgets, many countries are developing and implementing **programs to encourage use of generic medicinal products**. According to IMS Health data, in the US the increase in the share of generic medicines to 86 % by 2015 will result in savings amounting to USD 102 billion. The adoption of preferential policies and financial incentives encouraging doctors to prescribe generic medicines is also expected to take place in a number of other countries.

Bulgaria is faced with the same challenges to the innovation activity of pharmaceutical companies as the other EU member countries. In addition, Bulgaria strives to achieve **the lowest prices of medicinal products in the EU.** It is equally important to note the **limited market and the relatively high patient cost-sharing** for medications covered by public funds. **The market is characterised by delayed entry of innovative therapies due to a variety of organisational and financial reasons.**

The Bulgarian pharmaceutical industry is beyond doubt one of the priority sectors of the economy. Its role and development have been the object of various strategies elaborated in the past decade. At the same time, the emphasis has largely been on the industry as a whole rather than its innovation potential. The established public perception of innovations in this industry only in terms of their therapeutic value has led **Bulgarian manufacturers to concentrate their efforts exclusively on generic drug production and on achieving better prices**. A more detailed analysis of the latest products shows **increasing interest in the physical forms of medications** which inevitably affects the product's successful market performance.

There exist preconditions for the development of **open innovation in the pharmaceutical industry**. Yet it would seem that **the academic community, the industry and government institutions still do not fully appreciate the need for active collaboration among themselves and continue to adhere to a model where pharmaceutical innovations remain closed off behind the walls of production units or research laboratories.** The establishment of science and technology parks in the pharmaceutical area and promotion of the exchange of information on the basis of public-private partnerships could prove a successful approach in this respect.

Any steps taken by government authorities with respect to the pharmaceutical industry should be aimed at fostering a competitive environment with guaranteed patient access to innovative and safe medicines at affordable prices without unwarranted delays. This would include both measures to implement legislation in the area of competition and regulations aimed at improving the functioning of the market for the benefit of consumers. New policies and instruments furthering the development of the innovative potential of the

pharmaceutical industry are needed, including:

1. With regard to the **development of the national and sector-specific innovation system**:
- Encouraging interaction between science and industry;
- Investing in R&D infrastructure;
- Training of more highly qualified specialists through close collaboration with leading pharmaceutical companies;
- Establishing grants to ensure retention of young Bulgarian scientists and to attract international specialists;
- Supporting the development of R&D centres in cooperation with international pharmaceutical companies and IT companies;
- Prioritising the thematic areas related to pharmacy, medicine, and healthcare in the distribution of public funds for R&D through the National Science Fund and the National Innovation Fund;
- Encouraging public-private partnerships.

2. **Reducing the administrative burden**:
- With regard to the authorisation regime for the sale of new medicinal products;
- With the aim to speed up the entry of new medicinal products into the Bulgarian market;
- Reimbursement of new medicinal products at an earlier stage of their market entry.

3. **Effective communication of government medication and healthcare policy**:
- Choice of priorities regarding niche markets and manufactures/stages of the innovation process specific to Bulgaria;
- Balance between encouraging the production of generic and originator drugs;
- Improving the business environment for the pharmaceutical industry;
- Encouraging direct foreign investments in the pharmaceutical area;
- Transparency in the adoption of new regulatory requirements, including in connection with the processes of pricing and reimbursement of medicinal products;
- Improving the process of collection, processing, and analysis of statistical information and the use of real data in support of innovation planning.

The optimal use of resources is of particular importance to the stability of patient-centred health systems. That is why the Pharmaceutical Forum with the EC and the EC *Pharmaceutical Sector Inquiry Report* put forth recommendations to the member countries to this end. The national pricing and reimbursement systems need to ensure efficient use of price control, a package of measures concerning the supply and demand for medicinal products, and an adequate environment of price competition. These systems need to be aligned with systems that assess the value of medicines.

A key factor to the efficient use of medicinal products is providing citizens with accurate information. Healthcare is one of the sectors displaying most marked **information asymmetry**. Patients typically lack adequate information about the appropriate treatment and in many cases this results in the so-called 'dependence phenomenon' between the patient and the healthcare provider. Information asymmetry is one of the factors for the delayed patient access to generic medicines, together with delayed market entry of new drugs, excessive price control, low reimbursement rates, and the lack of measures to stimulate supply and demand.

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The Applied Research and Communications Fund is a Bulgarian research non-profit organization, registered in public benefit, established in 1991. Its mission is to support the development of innovation and the knowledge economy in Bulgaria through:

- advice and advocacy on establishing national, regional and local level policies and strategies for the country's successful integration into the global innovation economy;
- research and analyses of development trends and policy options for supporting innovation as well as information and communication technologies;
- public-private partnerships among businesses, public institutions, the academic community and civil society for addressing specific issues of ICT and innovation based competitiveness.

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