ΙΔΡΥΜΑ ΟΙΚΟΝΟΜΙΚΩΝ & ΒΙΟΜΗΧΑΝΙΚΩΝ ΕΡΕΥΝΩΝ
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A strategy study for the pharmaceutical industry

Executive Summary

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Structure of presentation

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II. The vision of the pharmaceutical industry

III. The National Research and Innovation System

IV. Contribution of the pharma industry to the national innovation system

V. Contribution of the pharma industry to the economy

VI. Obstacles to innovation

VII. SWOT analysis of the industry

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I. Today's economic and social environment

Until 2008: Low competitiveness and strong growth

❖Complacency: inability / indifference / postponement of addressing chronic structural problems of the Greek economy.

❖Deterioration in competitiveness performance revealed by international metrics (WEF, IMD).

❖As early as in 2008, the key pillars of growth (consumption and investment) began to weaken.

In 2009: Reform fatigue, systemic weaknesses

- ❖ Internationalisation deficits.
- ❖ Barriers to entry and distortions in markets.
- ❖ Big state, with ubiquitous involvement, but not growth-generating and not smart.
- ❖ Limited utilisation of research.
- ❖ Shallow and narrow entrepreneurship.

⇒ **In the context of globalisation and growing competition, Greek businesses face competitive pressures from both:**

❖producers in countries of low-cost labour moving away from low skills; and

❖higher-quality producers in countries with advanced living standards and significant technological and productive capacities

We seek high-quality growth based on knowledge, technology, innovation and driven by knowledge-intense entrepreneurship with the support of a smart and growth-friendly state

II. The vision of the pharma industry

Vision

Making the pharma industry the leading sector in the Greek economy in terms of output, R&D and service level.

Key requirements

Consultation –cooperation of the industry and the Greek state in designing a framework for supporting entrepreneurship and attracting new investment in the healthcare sector.

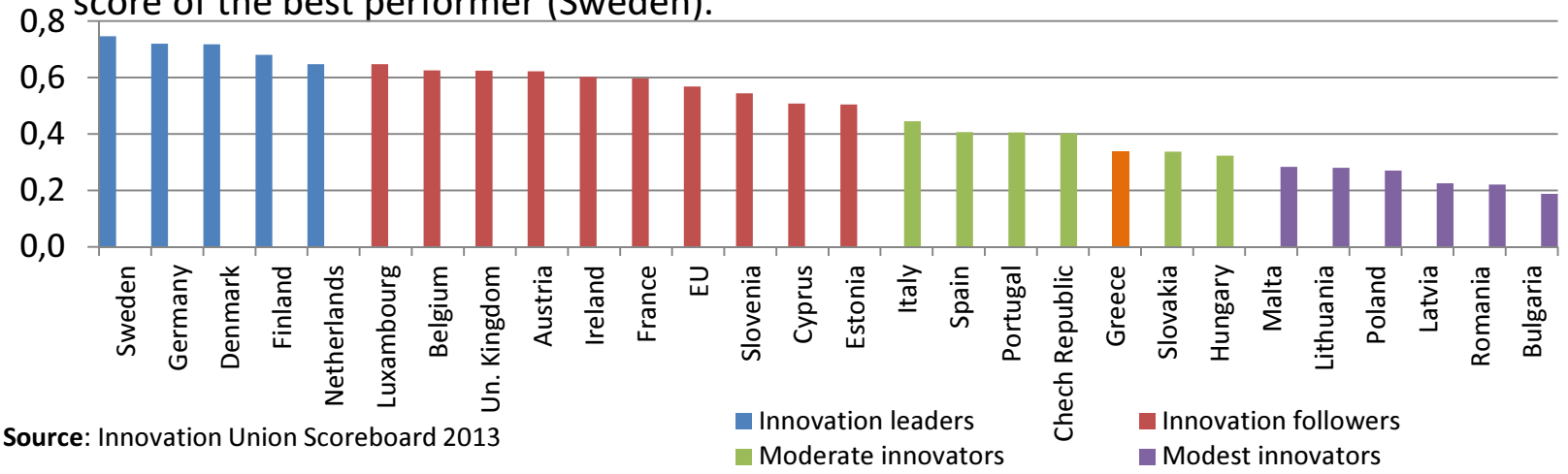
Strategic goals

- ❖Increasing R&D expenditure above 10% of companies' turnover in line with the target of "Europe 2020" (1.5% of GDP for R&D).
- ❖Making Greece a hub for clinical research (increasing annual expenditure on clinical research from EUR 84 million to EUR 400 million).
- ❖Increasing the number of medicinal patents.
- ❖Doubling investment in production plants in Greece.
- ❖Improving the competitiveness of Greek pharmaceuticals – increasing exports by 50%.
- ❖Linking academic/research centres with the industry to attract young scientists and researchers.
- ❖Promoting Greece as a major destination for conference and medical tourism.
- ❖Doubling employment in the pharma industry.

III. The National Research and Innovation System: overview

Low ranking of the country in competitiveness indicators

- Greece ranks 19th in the EU-27 (SII, 2013).
- Classified in "moderate innovators": At 63% of the EU average and about 44% of the score of the best performer (Sweden).



Source: Innovation Union Scoreboard 2013

Greece slow in transforming to a knowledge-based economy

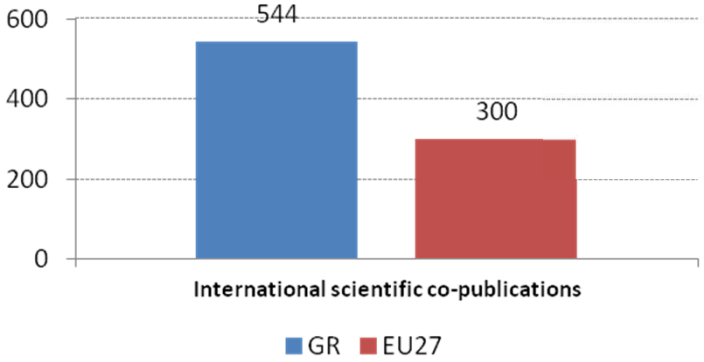
❖Relatively good score in terms of enablers (higher education graduates, public financing to businesses for innovation) and outputs (innovating SMEs as % of total SMEs, but mostly organisational innovation).

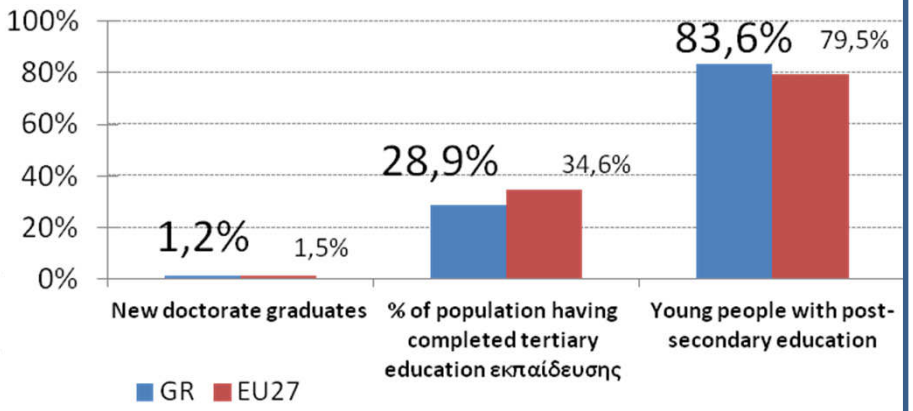
•But ... low rankings in most indicators (intellectual property rights, lifelong learning, private R&D expenditures).

•Mixed messages from businesses: easy innovation, shortfall in production of innovative technology- and knowledge-intensive industrial equipment.

III. The National Research and Innovation System: individual dimensions

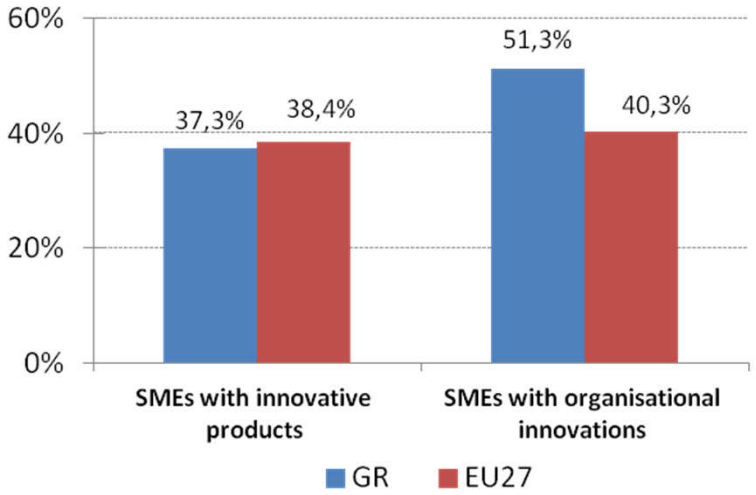
❖ Satisfactory education level of workforce





❖Large number and high quality of scientific publications

❖High innovation performance of Greek businesses, but mostly easy innovation (copying)

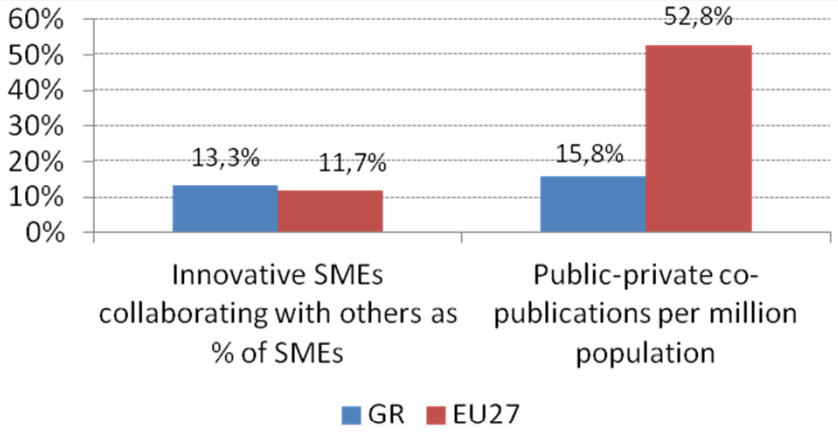


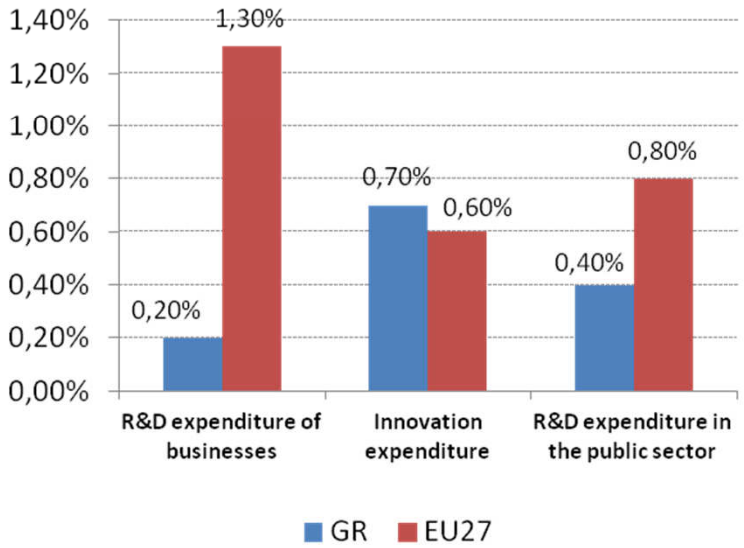
Source: Innovation Union Scoreboard, 2013

III. The National Research and Innovation System: individual dimensions

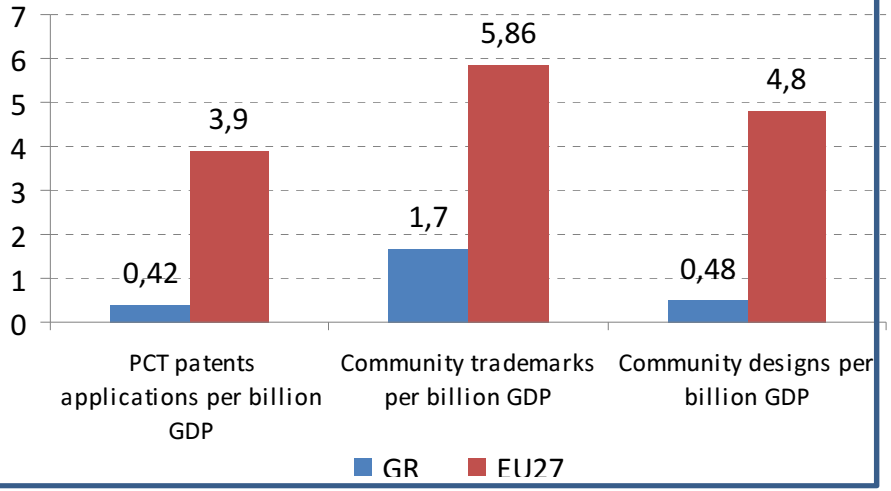
❖Weak cooperation between companies and universities/research centres, but also between companies

❖ But intensive collaboration between innovative companies





❖ Low R&D expenditures by all research sectors (businesses, universities, government, etc.)



❖But low patenting activity

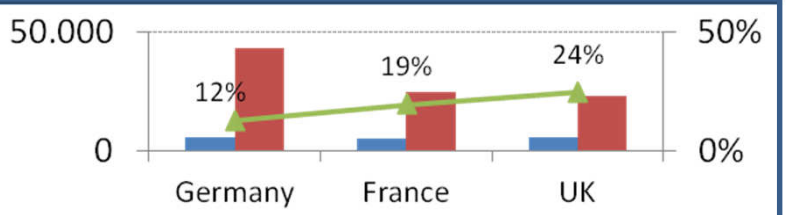
❖ Low commercialisation of research results

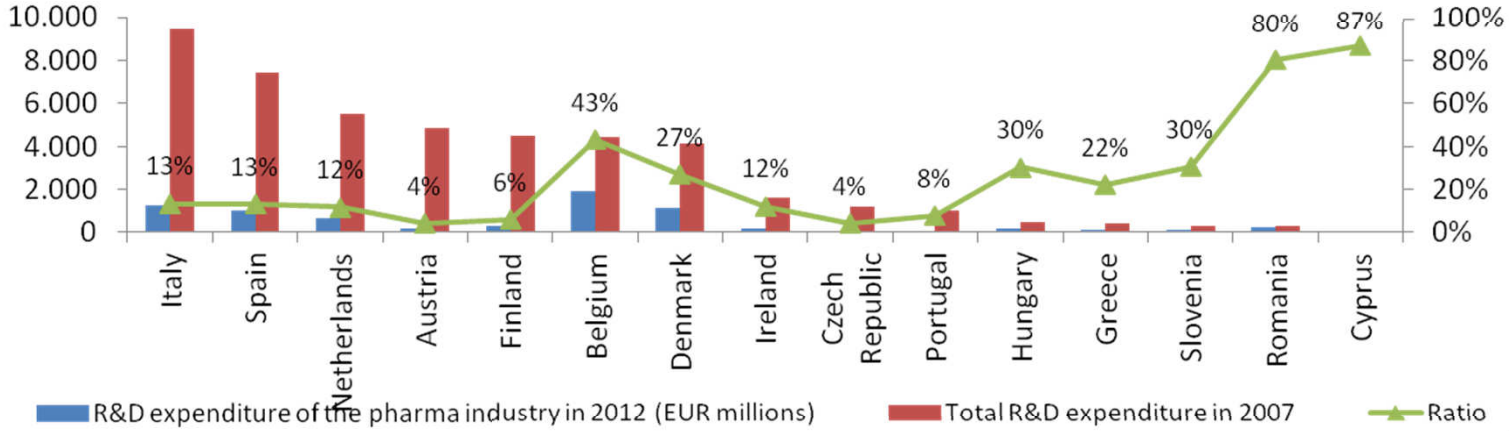
Source: Innovation Union Scoreboard, 2013

IV. Contribution of the pharma industry to the national innovation system

Greece: Low pharmaceutical R&D expenditure but relatively high share in total research expenditure

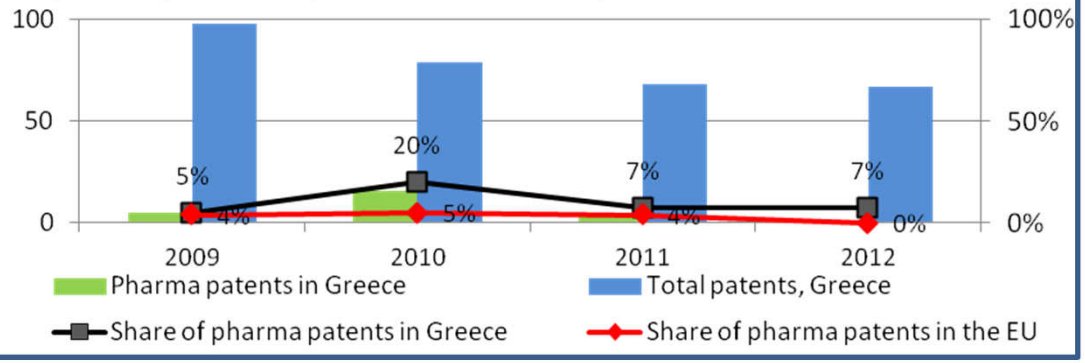
- In 2012, EUR 84 million for pharmaceutical R&D in Greece
- In Greece, 22% of total R&D expenditure accounted for by the pharmaceutical sector





Source Eurostat – SBS

- Higher share of pharma patents in Greece in comparison with the EU



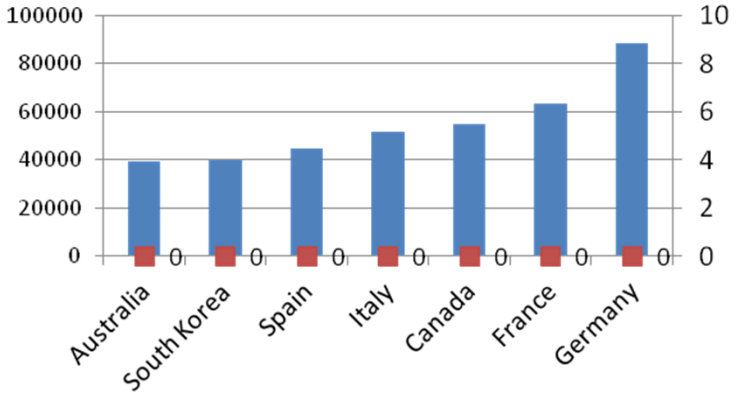
Source: European Patent Office.

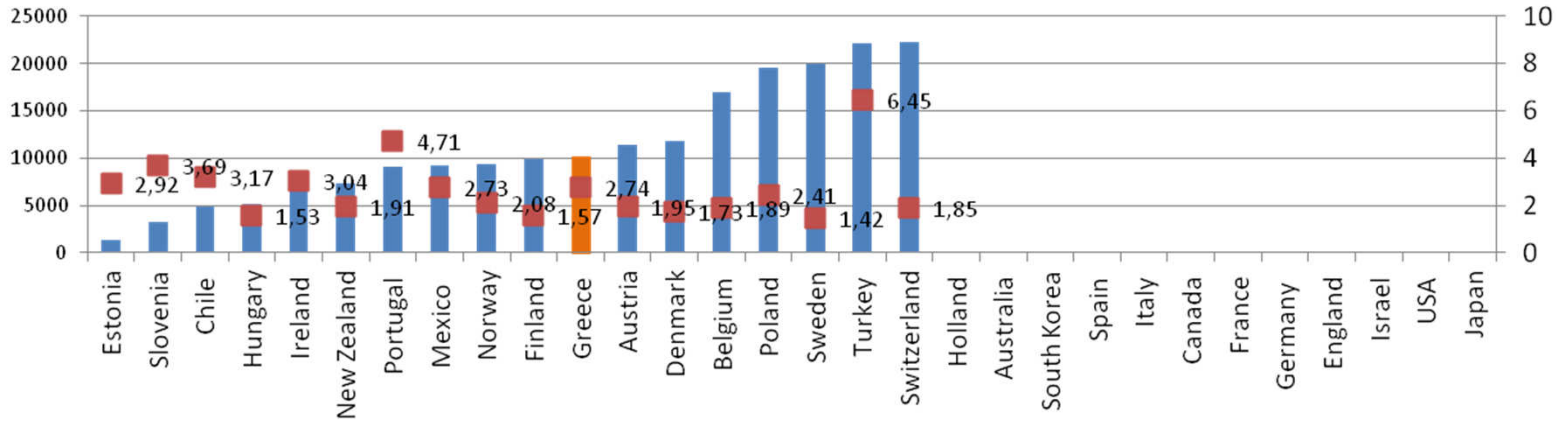
IV. Contribution of the pharma industry to the national innovation system

In 1996-2010, Greece among the best performers in growth of scientific publications

❖The number of scientific publications grew from 3,729 in 1996 to 10,219 in 2010, i.e. by a factor of 2.74, compared with average factors of 1.54 for the EU and 1.41 for the OECD countries.

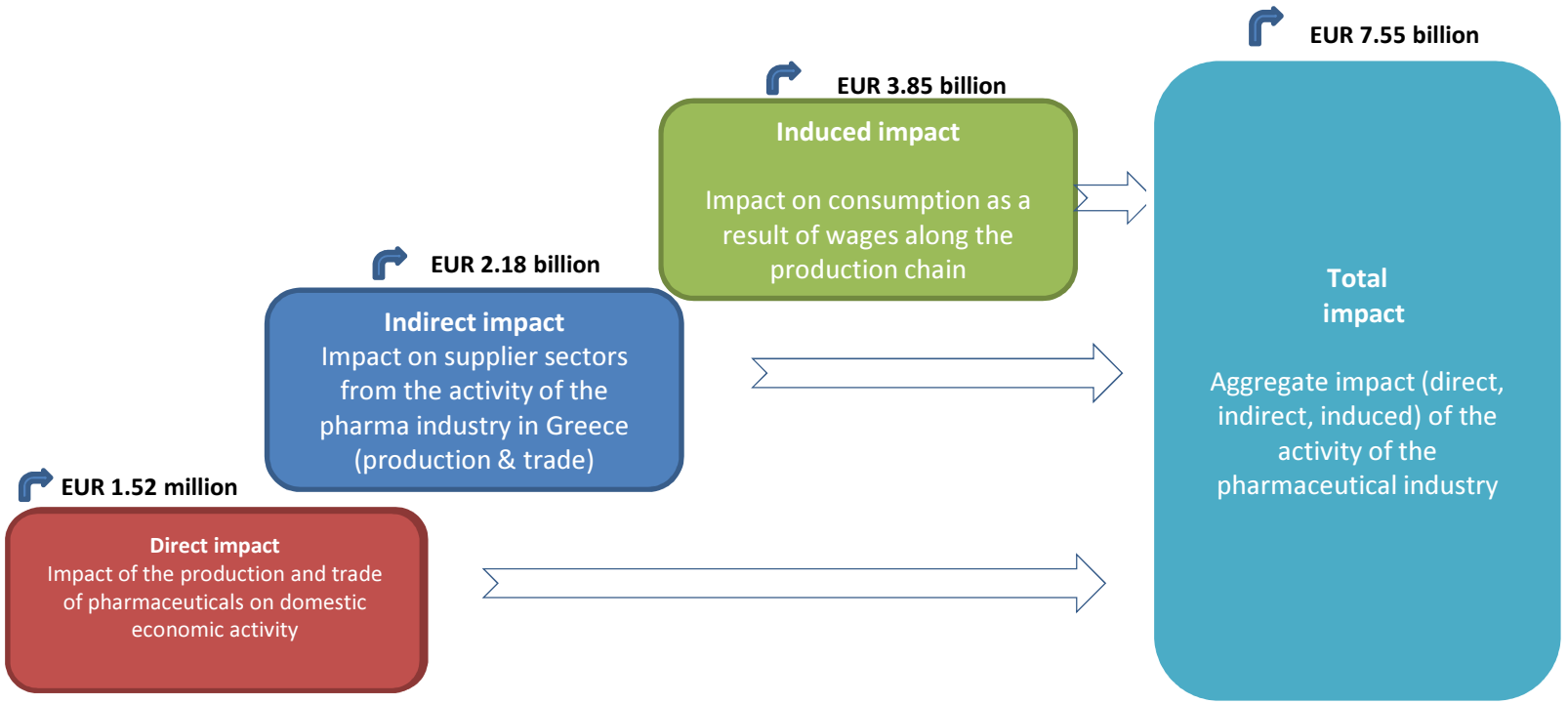
❖ Based on this factor, Greece ranks 8th among the 34 OECD member countries.





Source: Thomson Reuters, NSI 1996-2010.

V. Contribution of the pharma industry to the economy: impact on Gross Domestic Product



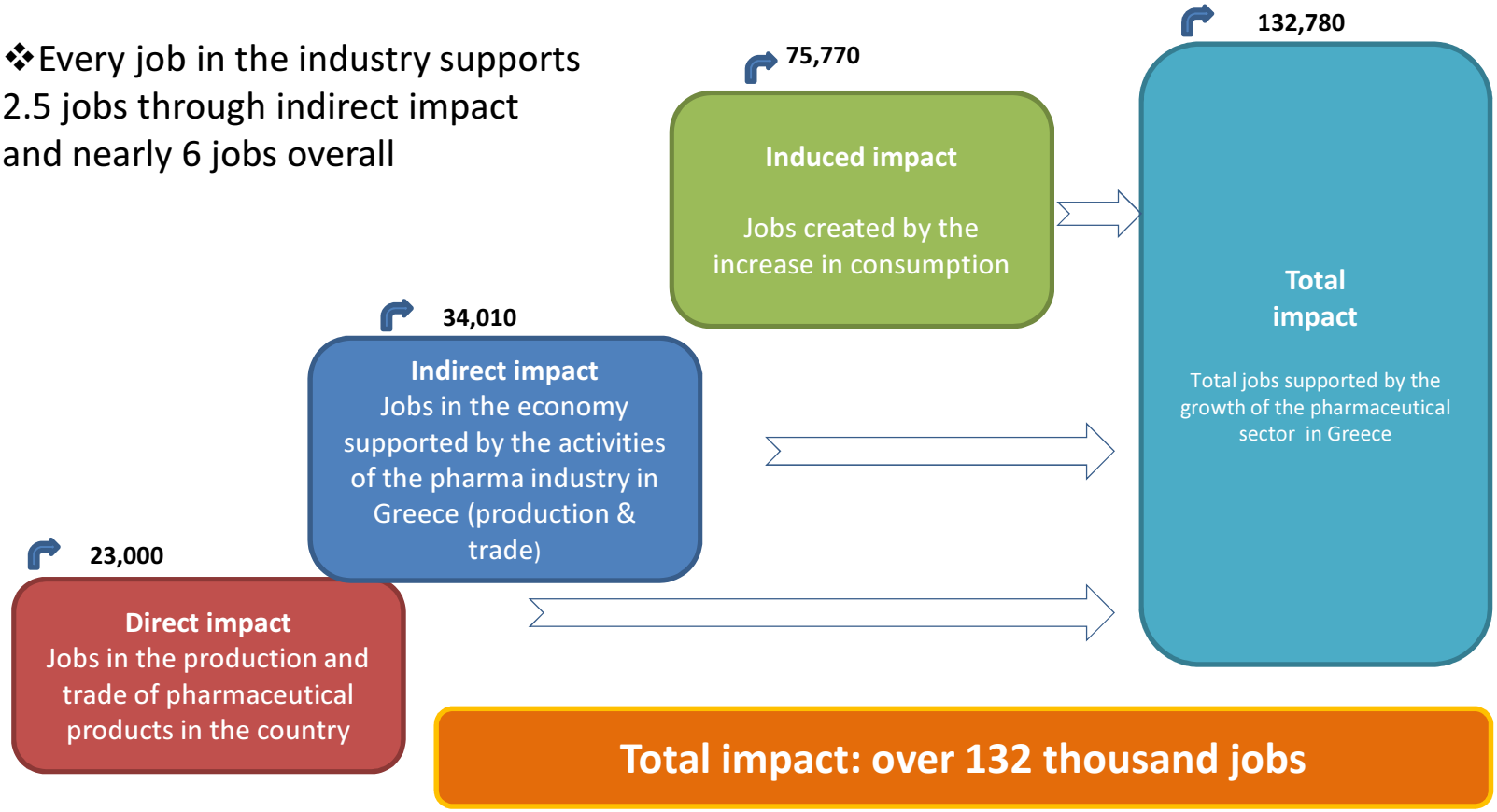
Source: Foundation for Economic and Industrial Research 2013, "The economic footprint of the production and distribution of pharmaceutical products in the Greek Economy".

! About 3.4% of the country's total GDP in 2010

- Every euro of value added in the production and distribution of pharmaceutical products leads to:
  - EUR 2.6 of value added through indirect impact; and
  - EUR 5.3 of value added if induced impact is also included.
- In terms of GDP, the multiplier is equal to 2.4 and 5 respectively

V. Contribution of the pharma industry to the economy: effect on employment

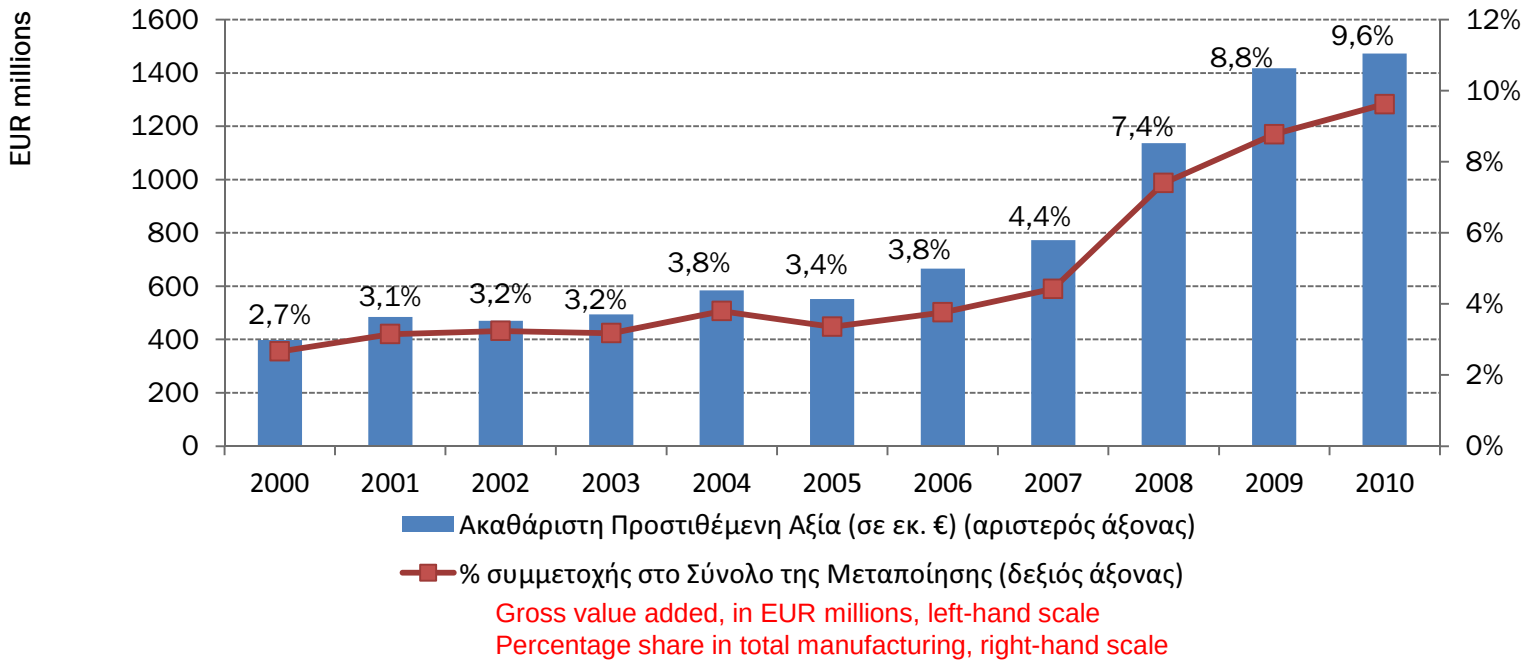
❖Every job in the industry supports 2.5 jobs through indirect impact and nearly 6 jobs overall



Source: Foundation for Economic and Industrial Research 2013,
"The economic footprint of the production and distribution of pharmaceutical products in the Greek Economy".

V. Contribution of the pharma industry to the economy: impact on the value added of domestic manufacturing

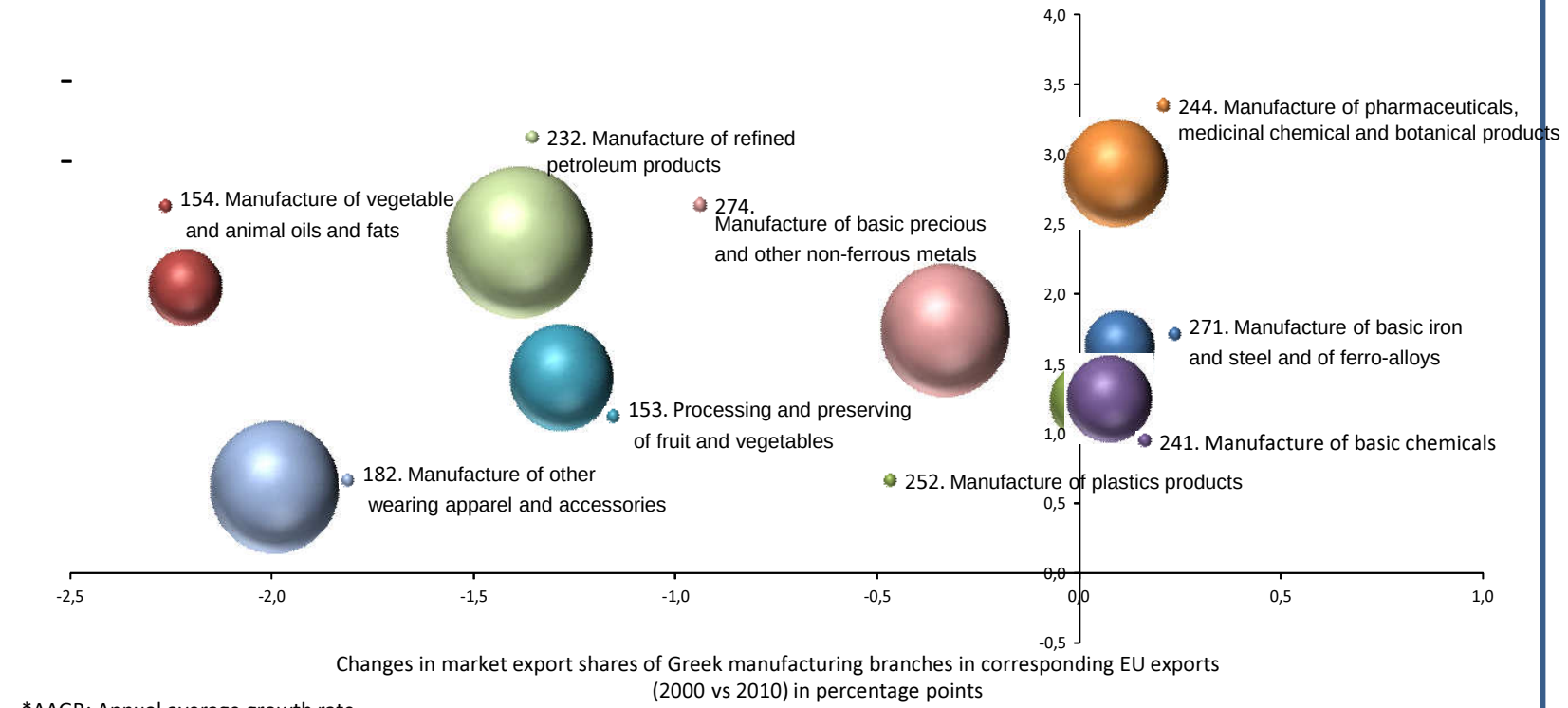
❖ The sector exhibits significant growth dynamics compared both with other domestic manufacturing industries and with respective sectors at European level



Source : ELSTAT, Eurostat – Note: Data classification according to NACE Rev. 2

V. Contribution of the pharma industry to the economy: Exports

Classification of manufacturing branches according to the shares of their exports in total Greek manufacturing exports



*AAGR: Annual average growth rate

The bubble size indicates the share of each branch in total Greek manufacturing exports.

VI. Obstacles to innovation

Obstacles relating to market organisation/operation – legal/institutional framework	Obstacles relating to human resources
❖Fragmentation in research ❖Difficulty in striking the right balance between generic/originator products and contribution to expenditure cuts ❖Lack of strategy to promote innovative entrepreneurship in the healthcare sector ❖Lack of coordination in the conduct of clinical studies in Greece ❖Frequent/ sudden changes in the institutional framework ❖Inadequate protection of intellectual property ❖Red tape and lack of a simple nationwide management system for clinical studies	❖Small research teams, lack of a critical mass ❖University administrative staff coordinating clinical research studies not adequately familiar with technology ❖Small percentage of Ph.D. holders employed in private sector ❖Weaknesses of the education system (emphasis on providing ready-made knowledge rather than engaging students in a creative process) ❖Risk of brain drain ❖Lack of intellectual property culture
Obstacles relating to networking	**Obstacles relating to financing**
❖Poor cooperation of businesses with universities/research centres ❖Lack of business partnerships (introversion, etc.) ❖Constraints on researchers' mobility, sporadic personal rather than institutional collaborations	❖High cost of innovation: requires investment in R&D that pays off in medium term, commitment of human and financial resources ❖Lack of a favourable business environment ❖Lack of appropriate innovation finance instruments for businesses

VII. SWOT analysis of industry

Strengths	Weaknesses
❖Health and pharmaceutical care: social good ❖Increase in the life expectancy of the population ❖Highly qualified human resources ❖Very good performance of researchers in terms of publications ❖Significant number of research centres/education institutions ❖Investment momentum, profitability and robust growth performance of firms in the sector (over the last 10 years) ❖ High-tech businesses and infrastructures	❖High cost of health and pharmaceutical care; new treatments more expensive ❖Surplus of doctors, shortage in nursing staff and other health professionals ❖Low investment of private funds in research ❖Low absorption of EU funds for research ❖Lack of link between research centres/ universities and industry ❖Low number of patents relative to the European average ❖Red tape (costs/barriers to starting up innovative businesses)

VI. SWOT analysis of industry

Opportunities	Threats
❖Rational allocation and management of human resources ❖Networking and cooperation between research institutions and small and large businesses ❖Further development of clinical research ❖Domestic production of generics ❖Production of new Greek medicines (new molecules or repositioning) ❖Development and export of specific diagnostic/imaging services ❖Expansion of activity to pharmaceutical and cosmetic products (essential oils, plants) ❖Development of medical tourism ❖Development of non-hospital care for the elderly and chronically ill ❖Greater integration of information technology, e-health and medical technology ❖Development of innovative substances and therapies (treatment of more diseases)	❖Worsening domestic socio-economic situation (economic crisis, unemployment, reduced incomes) ❖Brain drain ❖Sudden changes in the regulatory/legislative framework ❖Introversion of research and academic institutions

VIII. Action plan

PILLAR 1: Research, Development and Innovation

1.1 Developing policies for linking academic research centres and the private sector

- 1.1.1 Creating R&D clusters in cooperation with other stakeholders

1.2 Developing/revising the legislative framework for the protection and commercialisation of intellectual property rights on research results

- 1.2.1 Enhancing the operation of transfer technology offices in universities

1.3 Preserving and utilising the research potential

- 1.3.1 Creating research units within hospitals and linking existing units with the research cluster
- 1.3.2 Establishing a set of incentives to attract and retain researcher jobs in the private sector
- 1.3.3 Creating joint SFEE/PEF-University postgraduate programmes, focusing on research and business development

1.4 Strengthening the legislative framework, policies fostering the development of clinical research in Greece and licencing of medicines

- 1.4.1 Utilising existing clinical research infrastructure to attract foreign investment

PILLAR 2: Production and Exports

2.1 Introducing a favourable tax treatment of production and technological investment by the pharmaceutical industry

- 2.1.1 Amending tax rules in respect of intangible investment and profits from innovation

2.2 Increasing the extroversion and internationalisation of Greek pharmaceutical producers

- 2.2.1 Enhanced supervision and regulation
- 2.2.2 Establishing a one-stop shop structure for consultancy services to export firms
- 2.2.3 Using the Pharmaceutical Forum (EPhForT) as a network platform for exporters, to promote basic research, clinical research and domestically produced proprietary pharmaceuticals

1.1

PILLAR 1 PILLAR 1 PILLAR 1 PILLAR 1

1.1.1 Creating R&D clusters in cooperation with other stakeholders

- Exploring mature partnerships, embryonic networks, etc. which could develop into clusters
- Joining of forces between existing networks and provision of additional services to members
  - Advice from specialist patent lawyers
  - Partnerships with specialised universities and institutes, e.g. Johns Hopkins University.
- Identifying Greek success stories of innovative businesses, e.g. CBL Patras.

1.2

1.2.1 Enhancing the operation of transfer technology offices in universities

- Establishing contracts for technology transfer or licensing etc., specifying in detail the terms and conditions of transfer/licensing and the financial counterpart.
  - Compensation on royalties basis or up for payment and not in the form of equity holding in the spin-off
- Activation of transfer technology offices within in all academic institutions.
- Evaluation of staff (key performance indicators).
- Evaluation of structures (processes, results).
- Staffing with qualified personnel, e.g. patent lawyers with knowledge of procedures, costs, etc.
- Operation of technology liaison offices on the model of other European countries.

1.3

1.3.1 Creating research units within hospitals and linking existing units to the research cluster

- Systematic performance measurement of pharmaceutical research and innovation at national and regional level by institutional bodies, e.g. Hellenic Statistical Authority (ELSTAT).
- Encouraging research structures (National Health System, legal persons) through incentives to conduct clinical studies.
  - Improving and upgrading infrastructure for clinical studies.
- Deregulating the salaries of NHS and university researchers and physicians involved in clinical studies on medicinal products for human use.
  - Possibility of an additional fee for participation in research projects, by lifting or easing restrictions on the earnings of civil servants.
- Creating full-time jobs in hospitals for clinical researchers in charge of clinical trials and research activities.
- Reducing red tape under the existing legal framework (Joint Ministerial Decision 18910 on clinical trials, Article 18) in order to minimise unnecessary administrative procedures.
  - Utilisation of information technology (automation, databases).
- Establishing centres of clinical excellence and researcher networks within the National Health System.
- Utilising existing structures, e.g. Biomedical Research Foundation - Academy of Athens (BRFAA).
- Constantly updating legislation to keep it abreast of developments in science and technology (e.g. genomics) and in line with EU law.

1.3

1.3.2 Establishing a set of incentives to attract and retain researcher jobs in the private sector

- Changing the institutional framework, in terms of:
  - relaxation of employment restrictions for university teachers;
  - clarification of rules governing the participation of researchers and university teachers in the financial results of research that has translated into innovative business activity.
- Amending legislation on setting up a corporation to the effect that contribution of capital in the form of intangible assets (e.g. patents) can be freely negotiated/agreed by the contracting partners.
- Expanding internship schemes to more professions, e.g. pharmacists and chemists in pharmaceutical manufacturing companies.
- Encouraging the hiring of students after the end of internship by lower social security contributions for the first year.
- Employment in research in private-sector as qualification for academic career advancement.
- Encouraging employment of PhD holders in private companies.
  - Exempting businesses from employers' contributions for R&D staff.
- Employing researchers/university faculty members in the private sector (on contractual, project-specific basis).
- Funding of academic research by the private sector (e.g. scholarships to Ph.D. candidates).

1.3

1.3.2 Establishing a set of incentives to attract and retain researcher jobs in the private sector

- Rewarding innovation, supporting entrepreneurship and identifying innovative proposals in the field of healthcare through competitions/contests, e.g. SFEE Innovation Project
- Encouraging business ventures from university graduates, through joint actions of SFEE/PEF and universities (cf. the joint SEV-NTUA action “Starting up together”) .
- Maturing plans of students into business plans through a short-term boot camp with entrepreneurs and executives of pharmaceutical companies.
- Promoting a flexible and fast tool to provide seed capital finance to promising young scientists with innovative ideas that have the potential to translate into new medicinal products.
- Utilisation of the Research Potential Activity of the FP7 Capacities Programme, with a budget of EUR 340 million, for trans-national two-way secondments of research staff; acquisition and development of research equipment; organisation of workshops and conferences to facilitate knowledge transfer; evaluation facilities for research centres.

1.3

1.3.3 Creating joint SFEE/PEF-University postgraduate programmes, focusing on research and business development

- Creating postgraduate specialisation programmes (e.g. across university departments):
  - in the fields in biomedical engineering, clinical engineering, clinical research, pharmaceutical medicine, pharmacotechnology
  - interdisciplinary
- Involvement of the pharmaceutical industry in the development of postgraduate curricula in universities.
- Inclusion in the curricula of medical and pharmaceutical schools of subjects such as:
  - innovation, technology , ICT, licensing, commercialisation of knowledge
  - research methodology/ethics.
  - business administration, preparation of feasibility studies, business planning, access to finance.
- Organising business seminars as part of undergraduate and postgraduate programmes, e.g. on patents.
- Co-organising entrepreneurship summer school at international level, jointly by SFEE, PEF and Universities.

1.4

1.4.1 Utilising existing clinical research infrastructure to attract foreign investment

- Developing an institutional framework for the conduct of non-interventional studies which are an essential part of clinical research.
- Constant harmonisation of Greek legislation with EU law regarding the conduct of clinical trials of pharmaceuticals.
- Review of the institutional framework, organization and staffing of health facilities with adequate infrastructure for carrying out international Phase 1 studies (currently not available in Greece).
- Utilisation of incentives for cooperative research groups that can accelerate technology transfer from basic and clinical research to commercial applications and enable all stakeholders to have a better understanding of the problems to be solved and which may occur at various stages of the process.
- Recognition of clinical trials as scientific and technological research and the relevant expenditures as eligible for favourable tax treatment, to provide incentives for domestic growth and investment in research.
- Staffing the National Ethics Committee with scientific personnel properly trained to approve and supervise clinical trials and address regulatory and bioethical issues.
- Expanding the scope of the National Ethics Committee to include non-interventional clinical trials, diagnostic, surgical techniques, etc.; such tasks should be delegated to appropriate subcommittees, to ensure that the Committee’s core responsibility for interventional clinical trials is not affected.

2.1

2.1.1 Amending tax rules in respect of intangible investment and profits from innovation

- Revision of the tax break framework for R&D and technological innovation.
  - Removal or relaxation of the requirement that R&D expenses should exceed the average of previous two years to qualify for tax deduction (instead, R&D expenditure should exceed e.g. 50 % of previous year)
  - Stronger tax incentive, e.g. doubling the tax deduction, with or without a ceiling (tax after deduction should be at least 30% of the initial amount of tax).
  - Royalties should be exempt from withholding tax.
  - Possibility of exemption from social security contributions, as a bulwark against unemployment.
  - Application of a lower rate of corporate tax to profits earned from patented inventions and other innovations (cf. Patent Box in the UK).
- Creation of Special Economic Zones (SEZ) with special incentives, tax exemptions for corporations located in industrial areas/industrial parks.
- Amendment to Development Law to provide higher percentage of subsidy to manufacturing companies in regions with high industrial concentration, e.g. Attica.

2.1

2.1.1 Amending tax rules in respect of intangible investment and profits from innovation

- Removing tax impediments to production for non-resident companies (e.g. VAT charges, requirement to designate a tax representative resident in Greece, implying double taxation, difficulties in tax and accounting treatment).
- Harmonising Greek legislation with the EU Directive on deliveries of materials from EU countries under consignment arrangements.
- Setting up a committee of representatives of government and independent agencies to evaluate pharmaceutical companies' intangible investment (purchase of patents, marketing authorisations, clinical studies, etc.) for inclusion in the NSRF and other development programmes.
- Ensuring that the licensing process starts with the construction phase of capacity development/expansion projects (other than facilities expansion) for existing industrial plants. In any case, speedy issuance of necessary licences to avoid hampering investment and the smooth functioning of the market.
- Introducing tariff and tax exemptions and facilities for foreign firms relocating to Greece, e.g. an update of Law 89/1967 which was in force until 2005.

2.2

2.2.1 Enhanced supervision and regulation

- Enhancing the role of the National Organisation for Medicines (EOF):
  - Activation of MRP and DCP processes.
  - Speeding up the procedures for the evaluation and supervision of clinical studies conducted in Greece.
  - A supportive/advisory role for the pharmaceutical industry.
- Staffing with qualified human resources (e.g. Directorate of Pharmaceutical Studies and Research).

2.2

2.2.2 Establishing a one-stop shop structure for consultancy services to export firms

- Providing specialised consultancy services for firms seeking to export to new markets (on the model of Enterprise Europe Network - EEP), e.g. coaching, mentoring, training, infrastructure, support services.
- Activation of Enterprise Greece SA (which will result from the merger of Invest in Greece and the Hellenic Foreign Trade Organisation - OPE) to promote exports.
- Participating in international pharma and biotechnology events (e.g. CPHI, Bio-Europe on Generics from Greece) to co-promote Greek medicinal products and materials.
- Specialised training for one-stop shop staff.

2.2

2.2.3 Using the Pharmaceutical Forum (EPhForT) as a network platform for exporters, to promote basic research, clinical research and domestically produced proprietary pharmaceuticals

- Developing an electronic platform to encourage the sharing of R&A-related information among companies, universities and research institutes.
- Organising joint events, conferences and workshops between academia and the pharmaceutical industry for the purpose of promoting research institutes, disseminating research results and building mutual trust.
- Promoting international best practices in order to support innovative initiatives and strengthen the bonds between industry and research.

Sources of financing

- Bank lending.
- Joint fund with the participation of SFEE, Panhellenic Union of the Pharmaceutical Industry (PEF), TANEO, banks, VC, business angels.
- Mechanisms for jointly financing innovation and R&D, e.g. the Risk Sharing Financing Facility-RSFF, using funds of the European Investment Bank (EIB).
- Co-financed (e.g. NSRF) and national programs (Investment Law).
- Business angel networks.
- Special accounts for research grants at universities and research centres, e.g. ELKEA and/or ELKE (matching fund principle).
- Crowd funding.
- Public-private partnerships.